# Exhibit 6

| 1  | UNITED STATES DISTRICT COURT                 |  |
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| 2  | DISTRICT OF NEW JERSEY                       |  |
| 3  |  |  |
| 4  | IN RE: JOHNSON & JOHNSON MDL NO.:            |  |
| 5  | TALCUM POWDER PRODUCTS 16-2738 (FLW)(LGH)    |  |
| 6  | MARKETING, SALES PRACTICES,                  |  |
| 7  | AND PRODUCTS LIABILITY                       |  |
| 8  | LITIGATION                                   |  |
| 9  |  |  |
| 10 |  |  |
| 11 | EXPERT DEPOSITION OF                         |  |
| 12 | WILLIAM M. SAGE, MD, JD                      |  |
| 13 |  |  |
| 14 | Thursday, September 23, 2021                 |  |
| 15 | 8:13 a.m.                                    |  |
| 16 |  |  |
| 17 | Washington, DC 20006                         |  |
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| 19 |  |  |
| 20 |  |  |
| 21 | Reported by:                                 |  |
| 22 | Denise Dobner Vickery, NCRA Registered Merit |  |
| 23 | Reporter, NCRA Certified Realtime Reporter,  |  |
| 24 | Notary Public                                |  |
|    |  |  |

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|   | <sup>1</sup> APPEARANCES: (Continued)                            |
| 2   | 2  |
| 3   | <sup>3</sup> For Plaintiffs:                                     |
| 4   | 4 LEVIN PAPATONIO RAFFERTY PROCTOR                               |
| 5   | 5 BUCHANAN O'BRIEN BARR & MOUGEY, PA                             |
| 6   | 6 BY: CHRISTOPHER V. TISI, ESQ.                                  |
| 7   | 7 316 South Baylen Street, Suite 600                             |
| 8 Thursday, September 23, 2021                      | 8 Pensacola, FL 32502-5996<br>9 850 435 7176                     |
| 9 8:13 a.m.   | 030.433.7170   |
|   | ctisi@levinlaw.com   |
| Expert Deposition of Wileliam W. Stroe, W. S.       | 12   |
| held at the offices of:                             |  |
|   | 13 For Defendants Johnson & Johnson and Johnson &                |
| ABITCION I & OLINEE ELI                             | Johnson Consumer, Inc.:  SHOOK HARDY & BACON LLP                 |
| 15 1825 K Street NW                                 | SHOOK III IKD I & BI ICOIVEELI                                   |
| Suite 700   | B1. WHATE C. HEOTHET 1, ESQ.                                     |
| Washington, DC 20006                                | 2555 Giana Biva.   |
| 19  | 18 Kansas City, MO 64108<br>19 816.474.6550                      |
| Pursuant to notice, before Denise Dobner            | 20 mhegarty@shb.com  |
| 21 Vickery, Certified Realtime Reporter, Registered | 21   |
| 22 Merit Reporter, and Notary Public in and for the | 22 Also Present Remotely:  |
| 23 District of Columbia.                            | 23 KATE STONE, ESQ., Faegre Drinker                              |
| 24  | 24 Biddle & Reath LLP  |
|   |  |
| Page 3  |  |
| 1 APPEARANCES:                                      | 1 INDEX  |
| <sup>2</sup> <sup>3</sup> For MDL Plaintiffs:       | 2 EXAMINATION OF WILLIAM M. SAGE, MD, JD PAGE 3 BY MR. HEGARTY 8 |
| 4 BEASLEY ALLEN LAW FIRM                            | 4 AFTERNOON SESSION 213  |
| 5 BY: DR. MARGARET M. THOMPSON, ESQ.                | 5 DR. THOMPSON 426   |
| 6 218 Commerce Street                               | 6  |
| 7 Montgomery, AL 36104                              | 7 SAGE DEPOSITION EXHIBITS                                       |
| 8 1.800.898.2034                                    | 8 NUMBER DESCRIPTION PAGE  |
| 9 margaret.thompson@beasleyallen.com                | 9 Exhibit 1 Sage Invoice dated 8/10/2021 11                      |
| 10  | 10 Exhibit 2 Canada Screening Assessment 52                      |
| 11  | Talc, April 2021, Pages 1-65                                     |
| 12  | 12 Exhibit 3 Sage Curriculum Vitae 58                            |
| 13 For MDL Plaintiffs:                              | 13 Exhibit 4 7/2/2021 Expert Report of 75                        |
| 14 ASHCRAFT & GEREL LLP                             | 14 William M. Sage, MD, JD                                       |
| BY: MICHELLE A. PARFITT, ESQ.                       | 15 Exhibit 5 Literature from Expert Report 82                    |
| JAMES F. GREEN, ESQ.                                | 16 Pages 1-18  |
| 17 1825 K Street NW, Suite 700                      | 17 Exhibit 6 Second Amended Notice of Oral 96                    |
| 18 Washington, DC 20006                             | Deposition of William M. Sage, MD, JD                            |
| 19 202.759.7648                                     | and Duces Tecum,   |
| 20 mparfitt@ashcraftlaw.com                         | 20 Exhibit 7 HHS/Musser Letter dated 4/1/2014 151                |
| jgreen@ashcraftlaw.com                              | 21 Re two Citizen Petitions                                      |
| 22  | 22 Exhibit 8 NCI: Ovarian, Fallopian Tube, and 174               |
| 23  | 23 Primary Peritoneal Cancer                                     |
| 24  | Prevention (PDQ), Pages 1-20                                     |
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| <sup>1</sup> SAGE DEPOSITION EXHIBITS  | 1 PROCEEDINGS  |
| <sup>2</sup> NUMBER DESCRIPTION PAGE   | 2  |
| <sup>3</sup> Exhibit 9 NCI: PDQ Screening and Prevention 188   | WILLIAM M. SAGE, MD, JD  |
| 4 Editorial Board, Pages 1-2   | 4 called for examination, and, after having been   |
| <sup>5</sup> Exhibit 10 Sage Curriculum Vitae - Current 213  | buly sworn, was examined and testified as  |
| 6 Exhibit 11 Notebook: "William Sage, MD 220   | 6 follows:   |
| 7 Deposition Exhibits"   | 7  |
| 8 Exhibit 12 Regulatory Toxicology and 224   | 8 EXAMINATION  |
| 9 Pharmacology, Talc: Consumer   | 9  |
| 10 Uses and Health Perspectives, Carr  | 10 BY MR. HEGARTY:   |
| <sup>11</sup> Exhibit 13 Statement of Susan T. Mayne, PHD 248  | 11 Q. Good morning, Dr. Sage.  |
| 12 12/4/2019 "Building Consumer  | 12 A. Good morning.  |
| Confidence by Empowering FDA to  | Q. Would you please tell us your full  |
| 14 Improve Cosmetic Safety"  | 14 name?   |
| <sup>15</sup> Exhibit 14 IARC Monographs on the Evaluation 271   | 15 A. William Sage.  |
| of Carcinogenic Risks to Humans  | 16 Q. Who is your current employer?  |
| Arsenic, Metals, Fibres, and Dusts   | 17 A. The University of Texas at Austin.   |
| <sup>18</sup> Exhibit 15 Hopkins 28 List of Documents 277  | Q. Do you also have a separate personal  |
| <sup>19</sup> Exhibit 16 J&J Press Release: Company  | 19 consulting business for litigation?   |
| 20 Investigation Confirms No Asbestos  | A. Not for litigation. I have a  |
| in Johnson's Baby Powder 12/3/2019   | 21 Schedule C for any additional income I may make in  |
| 22 Exhibit 17 Pier 47 List of Documents 291  | <sup>22</sup> the course of the year doing academic-related  |
| 23 Exhibit 18 Talc Timeline 308  | 23 things.   |
| PCPC_MDL00062175 - 00062196  | Q. Are the is the income you earn as   |
|  |  |
| Page 7   | Page 9   |
|  |  |
|  | <sup>1</sup> an expert witness ran through this Schedule C <sup>2</sup> business?  |
| <sup>1</sup> SAGE DEPOSITION EXHIBITS  | <sup>1</sup> an expert witness ran through this Schedule C   |
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Page 10 Page 12 <sup>1</sup> BY MR. HEGARTY: <sup>1</sup> question. Have you ever been paid in any other Would you -- this is yours. <sup>3</sup> situation at the rate of \$800 an hour? A. Okay. Q. Specifically 800? No. Perhaps 750, Would you please look at Exhibit perhaps 6. The last time I did any expert witness <sup>5</sup> No. 1 and tell me whether that is an invoice that <sup>6</sup> work for a private party was many years -- was you prepared in connection with your work on this probably 10 years ago or so. MDL case. What was that expert witness A. Yes, it is. activity for a private party? May I just ask you. While we're 10 I was assisting two merging doing this, when you hand me things, what am I --11 am I supposed to keep them in a pile, return them hospitals in antitrust litigation. 12 Was that a matter in which you were to you? I don't know. <sup>13</sup> designated as an expert witness? 13 I would recommend you keep them in a Yes. Again, I'm not a litigator. pile as I may refer back to them. 15 <sup>15</sup> So I don't always get the procedural posture A. Okay. Thank you. <sup>16</sup> right. It was in anticipation of an 16 O. So with regard to Exhibit No. 1, <sup>17</sup> administrative trial before the FTC that didn't this is an invoice that you prepared; is that ever happen. correct? 19 Okay. You don't make \$800 an hour 19 A. Yes. as a professor at the University of Texas, right? 20 20 It's dated August 10, 2021 and lists O. 21 21 A. No. a total amount of \$64,000; is that correct? 22 22 Did anyone outside of perhaps the <sup>23</sup> lawyers for the plaintiffs in this case assist you 23 Have you been paid for this invoice? O. <sup>24</sup> in any way with preparing your expert witness 24 A. Yes. Page 11 Page 13 1 report? Have you prepared any other invoices 2 I'm sorry. Would you repeat that? besides the one we marked as Exhibit No. 1? A. 3 O. 3 A. No. Did anyone assist you in preparing Have you generated additional time <sup>5</sup> your expert witness report? in which you will invoice since preparing this I had assistance with formatting, invoice on August 10, 2021? <sup>7</sup> footnoting, and finding appropriate references A. Yes. <sup>8</sup> from the plaintiffs' lawyers. Q. How much additional time do you plan to invoice through today? If you can estimate it. Who in particular helped you with <sup>10</sup> those types of activities? 10 I haven't added it up. I would say Various people on the team and so, I 11 ballpark, if this was 80 hours, 40 hours. 12 mean, Dr. Thompson and then I know people more by Okay. With regard to this 13 first name. Patrick, Brianne. I don't remember particular invoice, in the "For" section you say 14 "Review of materials in preparation of expert <sup>14</sup> everybody's last name. 15 Did anyone outside of the lawyers 15 report from June 5 to June 2, 2021." <sup>16</sup> for the plaintiffs in any way assist you in 16 Does June 5 represent the first date preparing your report? 17 that you started working on this case? 18 18 No. So you said June 2. I think you

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MR. HEGARTY: I'm going to 20 mark as Exhibit No. 1 the invoice that we 21 have been provided from you by counsel 22 for the plaintiffs.

23 (Document marked for 24 identification as Sage Exhibit 1.) 20 July 2. I'm sorry. Q. 21 June 5th represents the first date <sup>22</sup> that I billed any time. All of my preliminary <sup>23</sup> discussions, investigations, deciding what the <sup>24</sup> case was about, and what my preliminary opinions

meant July 2 so...

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Page 14 Page 16 <sup>1</sup> might be I regarded as not billable. Were the -- when you say -- what was With regard to the reference below the preliminary outline of issues? <sup>3</sup> the "For" line to "Initial Meetings and Case That was perhaps my inartful way of <sup>4</sup> Review," who did you meet with initially that's saying thinking about the issues and how I would <sup>5</sup> referenced in that entry? express my opinions. To the best of my recollection, O. Was it a draft of your report? <sup>7</sup> these were Zoom meetings with people I hadn't Almost -- I don't know exactly how <sup>8</sup> necessarily met before, but Dr. Thompson, to answer that. I mean, it was my initial <sup>9</sup> Ms. O'Dell, Ms. Parfitt I think were the first thinking. So whether it constitutes a draft in my <sup>10</sup> significant call. And then Patrick and Brianne at notes or not, I really can't say. That's, I 11 some -- at some point early on, but I don't think, a matter of your practice and requirements. 12 <sup>12</sup> remember the details. Well, the entry below that does 13 That same line refers to an entry or <sup>13</sup> refer to "Preparing Expert Report." 14 refers to "Case Review." Do you see that? 15 15 What did you mean when you put in A. Yes. 16 <sup>16</sup> "Case Review"? So I see that as was it not two 17 Cutting me a little slack on the different activities, one preparing an outline and <sup>18</sup> terminology because I don't do this very often, I one drafting your report? <sup>19</sup> just meant this litigation. So, you know, 19 DR. THOMPSON: Object to form. <sup>20</sup> whatever materials were -- were offered to me or 20 THE WITNESS: I itemized them <sup>21</sup> whatever news reports I might have found just on 21 differently, I believe, to reflect the 22 <sup>22</sup> the posture of this litigation. I hadn't been stages of my thinking. I'm sure we'll 23 <sup>23</sup> following any of the individual cases, and I discuss much of this today. 24 <sup>24</sup> hadn't specifically been following multidistrict The stages of my thinking in Page 17 Page 15 <sup>1</sup> litigation. terms of an outline of issues just 2 thinking about: What are the The next line below the line 3 <sup>3</sup> "Initial Meetings and Case Review" says self-regulatory obligations? What are <sup>4</sup> "Preliminary Outline of Issues." 4 the disclosure obligations? You know, 5 Did you actually prepare a document 5 what are the differences between <sup>6</sup> where you outlined the issues? 6

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Not a -- not a structured document.

<sup>8</sup> My -- my own notes and my kind of musings about

<sup>9</sup> how -- how this would develop as a report.

10 Do you still have those notes? Q.

> I don't know, actually. A.

O. Were they handwritten or something

13 you typed on the computer?

11

12

14

19

2.0

21

Handwritten.

15 MR. HEGARTY: We would ask 16 that the doctor -- if you ask the doctor 17 to look for those notes. 18

DR. THOMPSON: And we'll object as draft of report.

MR. HEGARTY: Sure.

Understood, but we would ask that --

22 that -- well, let me back up before I

23 make the further request.

<sup>24</sup> BY MR. HEGARTY:

cosmetics regulations and drug regulations that are relevant?

Various things of that sort that are more general and almost certainly wouldn't have involved reviewing any corporate documents or -or deposition testimony from the litigation. Whereas, the deep dive is what followed that, and that's why I made the distinction.

MR. HEGARTY: Well, we'll make a request for those notes. I understand your objection. I just wanted to state it on the record and we'll do necessary follow-up, okay?

DR. THOMPSON: (Nods head).

BY MR. HEGARTY:

23 The University of Texas has <sup>24</sup> disclosure policies for all work outside of your Page 18

<sup>1</sup> job; is that right?

- <sup>2</sup> A. Yes.
- Q. Have you disclosed the work you're
- doing in this litigation pursuant to that policy?
   A. I've disclosed everything that's
- <sup>6</sup> required to be disclosed and received any approval
- <sup>7</sup> that was required to be received.
- Q. As it relates to this case, correct?
- <sup>9</sup> A. Yes.
- Q. Did you have to prepare a written
- <sup>11</sup> report disclosing your work on this case?
- A. Only in the most general terms.
- Q. But you actually prepared a report
- <sup>14</sup> and submitted it to someone?
- A. I filled out an online form.
- Q. Do you have a copy of that online
- $^{17}$  form?
- <sup>18</sup> A. No.
- Q. Did you have to get approval to do
- <sup>20</sup> this work?
- A. I did have to get approval to do
- <sup>22</sup> this work.
- Q. Who did you have to get approval
- 24 from?

Page 19

- <sup>1</sup> A. I had to get approval from whoever <sup>2</sup> was the designated individual to grant approval.
- <sup>3</sup> I identified the vice dean at the University of
- <sup>4</sup> Texas Law School, who granted approval.
- Q. What -- in what form was the
- <sup>6</sup> approval granted?
- <sup>7</sup> A. A click on a website.
- <sup>8</sup> Q. Click on a website to see if it says
- <sup>9</sup> granted?
- In other words, how was it done?
- <sup>11</sup> Was it done by an e-mail or was it done by a phone
- <sup>2</sup> call? Was it done by an in-person sign-off?
- A. Would you like me to outline the
- <sup>14</sup> process as best as I can recall it?
- Q. All I'm really looking for is: In
- <sup>16</sup> what form did you get the approval?
- A. I submitted the form. There are --
- <sup>18</sup> there are independent requirements at the
- <sup>19</sup> University of Texas and, as you probably know,
- <sup>20</sup> this is an area that's in flux at many
- <sup>21</sup> universities.
- I also have a significant academic
- <sup>23</sup> expertise in conflict of interest and conflict of
- <sup>24</sup> commitment policy. So I pay attention to all of

Page 20

- <sup>1</sup> this, including when I'm teaching professional
- <sup>2</sup> responsibility classes.
- The way that the University of Texas
- 4 system currently works, they have centralized the
- <sup>5</sup> approval of outside activities that would
- <sup>6</sup> constitute conflict of commitment; in other words,
- <sup>7</sup> that might take time away from one's teaching
- <sup>8</sup> obligations to the university. They centralized
- <sup>9</sup> those at the University of Texas system level.
- 10 The University of Texas is comprised of several
- <sup>11</sup> campuses.

18

23

3

- That particular form asked me a
- number of questions which I filled in on the form
- $^{14}\,$  and asked me to identify the person who would
- <sup>15</sup> grant approval. I designated the vice dean at the
- <sup>16</sup> law school because he's the person I would expect
- <sup>17</sup> to grant approval.
  - Nothing happened for a while. I
- <sup>19</sup> reached out to him. He investigated, found that
- <sup>20</sup> he could grant approval, granted approval, told me
- <sup>21</sup> he had granted approval, and the next time I
- <sup>22</sup> checked the website approval had been granted.
  - Q. Okay. What is his name?
- A. Robert Chesney.

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- Q. Have you otherwise advised anyone at
- the University of Texas of your work on this case?
  - A. No.
- 4 Q. What courses are you teaching, if
- <sup>5</sup> any, this summer -- this semester?
- 6 A. So this semester I'm a visiting
- <sup>7</sup> professor here in Washington, DC at the George
- 8 Washington University Law School, and I'm teaching
- <sup>9</sup> -- that is a standard turnkey operation where the
- <sup>10</sup> University of Texas remains my employer. I am
- 11 only paid by them, and they have a separate
- <sup>12</sup> agreement in a standard fashion for visiting
- professorships with the institution that is
- <sup>14</sup> hosting the semester.
- And at GW, I'm teaching a
- <sup>16</sup> three-credit legislation and regulation course,
- <sup>17</sup> which is my standard regulatory theory and
- 18 regulatory design class, and I'm teaching a
- inguinately design enast, and im teaching a
- <sup>9</sup> for-credit health law and policy survey class.
- Q. Have you taught classes either as a
- <sup>21</sup> visiting professor or at the University of Texas
- <sup>22</sup> ever since you started at Texas? In other words,
- 23 have you taught classes every semester either at
- <sup>24</sup> Texas or somewhere else since you started?

No. I have occasionally had a <sup>2</sup> research semester, or I've had additional teaching

- <sup>3</sup> credit, or I've had an eminent scholar fellowship
- <sup>4</sup> that would relieve me of teaching. But I really
- <sup>5</sup> like to teach, so I usually teach the equivalent
- <sup>6</sup> of a full load every year.
- Did you teach classes every semester while at Columbia?
- Columbia, unlike the University of
- <sup>10</sup> Texas, has a structured sabbatical program. So <sup>11</sup> not when I had a formal sabbatical, and I believe
- <sup>12</sup> also not when I had large research grants that the
- 13 law school based relief of teaching on. But, in
- <sup>14</sup> general, I teach every semester and, in general, I
- 15 teach a full or an overload. I'm teaching an
- overload this semester.
- 17 Since 2001, have you been a
- 18 full-time law school professor?
- 19 Since 1995, I've been a full-time
- 20 law school professor. 21
- Q. 1995.
- 22 And the courses you have taught
- since 1995 have all been in a law school, correct?
- 24 I am interdisciplinary by training. A.

<sup>1</sup> courses. I may be teaching them about advocacy.

- <sup>2</sup> I'm often teaching them about professional
- <sup>3</sup> responsibility. I teach my professional ethics
- <sup>4</sup> classes from a comparative professions perspective
- <sup>5</sup> and do a lot of law/medicine comparisons and
- occasionally other professions also.
- But you're not teaching the practice of medicine, correct?
- A. I'm not teaching clinical medicine, 10 no.
- 11 And you've never taught clinical O. medicine to gynecologic oncologists, correct?

13

14

- Q. You have not taught clinical
- medicine to oncologists, correct?
- I have not taught clinical medicine.
- You can ask -- you can subdivide that all you
- want. I have not taught clinical medicine.
- 19 You don't teach epidemiology,
- 20 correct?
- 21 I teach -- I use epidemiological
- <sup>22</sup> materials in a fair amount of my regulatory
- teaching. I mean, we consider all sorts of
- <sup>24</sup> preventive screens and tests. We do a lot of

Page 23

- <sup>1</sup> I am dually tenured in both the law school and
- <sup>2</sup> medical school at University of Texas. My last --
- <sup>3</sup> before GW, my last visiting professorship at NYU,
- <sup>4</sup> I had a visiting professor appointment both in law
- <sup>5</sup> school and at NYU School of Medicine.
- And virtually all of the classes I
- <sup>7</sup> teach at my home institution are cross-listed in
- <sup>8</sup> business and public affairs and in the medical
- <sup>9</sup> schools, and I typically design my courses to
- attract enrollment from many different schools.
- 11 So in your career as a professor, you have taught medical students?
- 13 Indeed, many times.
- 14 When is the last time you had a
- course in which you taught medical students?
- Last spring I taught my health, law,
- and policy class at Texas and had over a dozen third-year medical students enrolled, which an
- entering class of 50 is a significant number of the medical school class. So I'm actually very
- proud of how many medical students I teach.
- 22 When you teach medical students, 23 you're teaching them law-related courses, correct?
  - I'm teaching them policy-related

<sup>1</sup> basic epidemiological calculations. I do have

public health students in my classes from time to

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- <sup>3</sup> time, but, no, I've never taught a course in
- <sup>4</sup> epidemiology.
  - O. You don't teach courses in
- toxicology, correct?
- No, I don't.
- Q. Have you ever taught any courses on
- FDA's cosmetic regulations?
- I teach FDA-related issues
- constantly, including within the last week. I've
- never used a cosmetic regulatory example in my
- 13 teaching.
- 14 O. Have you ever taught courses on the
- manufacturing of cosmetics?
- 16 Have I ever taught courses on the
- 17 manufacturing of cosmetics? No.
- 18 Have you ever taught courses on the marketing of cosmetics? 19
- I have taught -- I've -- when you
- 21 say "course," do you mean an entire semester
- course or do you mean a class session or part of a
- class session?

24

O. Well, have you ever -- let me ask it

24

Page 26 Page 28 1 In terms of my statement in <sup>1</sup> a different way. 2 paragraph 7 of my report, I was trying to Have you ever taught about the <sup>3</sup> marketing of cosmetics specifically as to 3 lay out the general expertise that would 4 4 cosmetics? relate to the specific topics in the 5 Again, I've taught about the A. report. <sup>6</sup> marketing of drugs. I've taught about the BY MR. HEGARTY: <sup>7</sup> marketing of many things. I don't believe I've Tell me when you first read the FDA cosmetic statutes and regulations that you cite in <sup>8</sup> ever taught specifically about the marketing of your report. cosmetics. 10 Have you ever taught specifically 10 Q. A. The cosmetic-specific regulations I about the labeling of cosmetics? <sup>11</sup> first read as I was deciding whether I would 12 No. Again, with the caveat that I accept the invitation to serve as an expert <sup>13</sup> witness. The underlying pillars of FDA <sup>13</sup> teach about labeling and information disclosure <sup>14</sup> regulations regarding, say, adulteration and all the time. 15 <sup>15</sup> misbranding, which are applicable to cosmetics, Have you ever taught any courses Q. about the testing of cosmetics? <sup>16</sup> the general history of the Pure Food and Drug Act, 17 <sup>17</sup> of the Food, Drug, and Cosmetic Act of 1938, I A. No. 18 <sup>18</sup> have been teaching this my entire career and have Q. Have you ever taught a course on Canadian cosmetic regulatory law? read them many times. 20 20 A. But prior to being contacted as No. 21 potentially serving as expert witness in this Q. Have you ever taught courses on FDA <sup>22</sup> case, you had never read the cosmetic statutes and <sup>22</sup> regulations as they relate to drugs, medical devices, or over-the-counter medications? regulations that you cite in your report, correct? 24 I've taught many class sessions that DR. THOMPSON: Object to form. A. Page 27 Page 29 <sup>1</sup> involve those issues. I've never taught a THE WITNESS: Again, I had 2 <sup>2</sup> semester-long FDA law class. read the general statutes because the 3 There is a course at University of general statutes are applicable beyond <sup>4</sup> Texas called "Food Safety Law" that gets into FDA cosmetics. I had not read the CFR <sup>5</sup> regulations. entries for cosmetics. You've never taught that class, have BY MR. HEGARTY: <sup>7</sup> you? So in particular, prior to being A. I have not taught that. contacted by plaintiffs' lawyers in this case, you Q. In paragraph 7 of your report, you had never read 21 CFR 740.1, correct? 10 <sup>10</sup> say that your expertise is in the science of DR. THOMPSON: Object to form. policy-making, including the science of regulatory 11 THE WITNESS: So, again, I'm <sup>12</sup> design. 12 just going to take the liberty of -- of 13 13 when we're doing code sections, even You go on to say that you are an 14 <sup>14</sup> expert in government-supervised health and though I'm pretty sure I know which ones <sup>15</sup> financial self-regulations, corporate compliance 15 you're referring to or CFR sections, I'm <sup>16</sup> and corporate governance, and the regulations of 16 just going to have them around so that I 17 self-governing professions. 17 can -- I can --18 Nowhere in your report do you list BY MR. HEGARTY: 19 <sup>19</sup> any expertise in FDA cosmetic regulations, Q. correct? 20 -- make sure I answer you A. 21 DR. THOMPSON: Object to form. accurately. 22 22 THE WITNESS: I think a lot So you were regarding --23 23 of my report is certain proceedings and Q. 24 24 FDA cosmetic regulations. A. -- the warning statements on

Page 32 <sup>1</sup> cosmetics specifically? No, I had not read that <sup>1</sup> being hired to work on this case? <sup>2</sup> section prior to considering these issues. DR. THOMPSON: Object to form. You're not an expert in FDA cosmetic 3 THE WITNESS: I have not done 4 <sup>4</sup> regulations. True? specific work on cosmetic regulations I --5 prior to my involvement with these A. 6 6 DR. THOMPSON: Object to form. issues. 7 THE WITNESS: I consider BY MR. HEGARTY: 8 myself an expert in cosmetic regulations. Had you ever heard the term 9 It's a short number of regulations that "asbestiform" before being hired in this case? 10 fit in a larger scheme that I have great 10 DR. THOMPSON: Object to form. 11 11 familiarity with. THE WITNESS: I have an 12 12 BY MR. HEGARTY: undergraduate degree in biochemistry that 13 13 included a couple of geology classes. So Would you have called yourself an 14 14 expert in FDA cosmetic regulations prior to being chances are, yes, but I don't recall. contacted by the plaintiffs' counsel in this case? BY MR. HEGARTY: 16 DR. THOMPSON: Object to form. 16 Had you ever heard the term 17 17 THE WITNESS: I'm not sure I non-asbestiform before being hired? 18 18 know the answer to that. It would have Α. Same answer. 19 19 depend on the context I was being asked DR. THOMPSON: Object to form. 20 the question. BY MR. HEGARTY: 21 21 I wouldn't have asserted that Had you ever heard the term 22 <sup>22</sup> "elongated mineral particles" before being hired as a focused expertise, but I would have 23 in this case? understood that a small amount of -- of 24 24 intense research would be sufficient to DR. THOMPSON: Object to form. Page 31 Page 33 1 connect what was specific to cosmetic THE WITNESS: Elongated 2 2 regulation to my general food, drug, and mineral particles was an interesting 3 3 cosmetic expertise. So probably I would acronym. My impression is it's 4 4 have. relatively new. So I don't believe I had <sup>5</sup> BY MR. HEGARTY: ever heard that before. Even though you had never read the BY MR. HEGARTY: cosmetic regulations, correct? Had you ever heard the phrase "fibrous talc" before being hired in this case? DR. THOMPSON: Object to form. 9 9 THE WITNESS: (Laugh). Yes. DR. THOMPSON: Object to form. 10 10 THE WITNESS: Again, I don't BY MR. HEGARTY: 11 11 Okay. Fair enough. know. O. 12 Tell me -- well, strike. Let me 12 BY MR. HEGARTY: 13 back up. Have you ever been designated as an expert witness in any lawsuit before this one? Have you had any formal training, <sup>15</sup> formal courses on FDA cosmetic regulations and 15 As we were discussing earlier, I 16 practices? <sup>16</sup> served as a named expert, but did not ultimately 17 testify in a hospital antitrust suit involving two A. I have not taken any formal courses <sup>18</sup> on cosmetic regulation. I have taken -- I have private hospitals in Illinois and the Federal 19 attended many talks and read many papers and Trade Commission, roughly, 10 years ago, maybe 12. <sup>20</sup> attended conferences involving FDA issues overall Any time other than that instance <sup>21</sup> several times. 21 that you are aware of you've been actually <sup>22</sup> designated or identified as an expert witness in a 22 Focusing specifically on cosmetic <sup>23</sup> regulations, can you cite for me all the work you 23 lawsuit? <sup>24</sup> have done concerning cosmetic regulations before 24 A. No.

Page 34

You received both a law and medical <sup>2</sup> degrees -- or let me rephrase that.

You received both law and medical <sup>4</sup> degrees at Stanford, correct?

A. Correct.

Which one did you complete first? 6 O.

(Laugh). There are many ways to answer that question.

I entered medical school first. I

<sup>10</sup> entered law school near the end of my third year

<sup>11</sup> of medical school. I integrated the two programs,

<sup>12</sup> and I received both degrees the same day.

13 After one year of residency in <sup>14</sup> anesthesiology, you went to work at a law firm in

<sup>15</sup> Los Angeles; is that correct?

Not -- not exactly. I did -- I

<sup>17</sup> completed an internship year in what's called the

<sup>18</sup> transitional year Internship in San Diego, which

19 would have been the first year of a four-year

<sup>20</sup> anesthesia residency. I then completed the second

<sup>21</sup> year of that residency at Johns Hopkins, you know,

<sup>22</sup> in the normal course, and having completed that

<sup>23</sup> year, I then moved back to California and became

<sup>24</sup> an associate at a law firm.

21

Page 35

Why did you stop practicing Q. <sup>2</sup> medicine?

A. My -- my intent was to acquire <sup>4</sup> practice experience in each profession and to go

<sup>5</sup> back and forth between the two until I had a good <sup>6</sup> grounding in both.

7 When is the last time you treated a Q. 8 patient?

Α. I have an active Texas medical

<sup>10</sup> license. I do not maintain a clinical practice.

<sup>11</sup> I do my best to keep my clinical skills up, but I

<sup>12</sup> don't treat patients. So the last time I treated

<sup>13</sup> a patient in a formal sense was during my second

<sup>14</sup> year of postgraduate training so as an anesthesia

<sup>15</sup> resident at Johns Hopkins.

16 What year was that? O.

17 A. That would have been 1990.

18 Q. You went to work at O'Melveny in Los

19 Angeles, correct?

> A. Correct.

21 Q. And you were an associate in the

<sup>22</sup> corporate group; is that right?

23 Yes. A.

20

24

O. And your CV says you worked on cases <sup>1</sup> related to public finance, securities, mergers and

<sup>2</sup> acquisitions?

A.

O. You were an associate at O'Melveny

<sup>5</sup> for four years before leaving to become a law professor?

I was an associate for -- an

associate from October of 1990 until January of

<sup>9</sup> 1993, when I resigned in order to work in the

<sup>10</sup> White House on that era of Clinton Administration

<sup>11</sup> health reform. And then the following September,

perhaps October, I rejoined O'Melveny on a half

time basis and I worked there until I became a law

professor in 1995.

15 Are you aware that O'Melveny

represents Johnson & Johnson?

A. I am. John Beisner was someone I

<sup>18</sup> knew slightly when I worked in the DC office on

Supreme Court litigation during my otherwise

corporate practice years.

So you did work with lawyers

<sup>22</sup> representing Johnson & Johnson?

DR. THOMPSON: Object to form.

24 THE WITNESS: No. I knew

Page 37

Page 36

that John Beisner was in the office and

said hi to him a few times.

<sup>3</sup> BY MR. HEGARTY:

Did you ever work on any matters

involving Johnson & Johnson?

A. No.

What percentage of your working time

this year has been spent on litigation matters?

A. Would you rephrase that?

9

10 Sure. O.

12

15

21

11 A. Sorry.

> O. Are you working on any litigation

matters as an expert witness besides the one we're

here to talk about today?

A. No.

16 How much time have you spent -- I

guess, let me back up.

The time you've spent working on

19 this case has been in 2021, correct?

20 Α. Correct.

> O. And it's been the time we talked

<sup>22</sup> about in the invoice, plus the other time you

<sup>23</sup> billed since that time; is that right?

A. Correct.

Page 40 1 Have you ever been hired by a Q. Did you earn any fees as an expert Q. witness in 2020? <sup>2</sup> company to consult with regard to a prescription 3 drug? 3 No. Α. 4 4 How about 2019? A. No. Q. 5 May I just ask. When you say "hired 6 <sup>6</sup> by a company," I haven't, to my knowledge, been Q. Before this case, have you ever been <sup>7</sup> designated as an expert to testify about <sup>7</sup> hired by anybody for these purposes. But when you cosmetics? 8 say "a company," do you mean by, I mean, as 9 <sup>9</sup> opposed to a law firm or do you mean just all Α. No. 10 10 others? Q. Before this case, have you ever been 11 designated as an expert to testify about cosmetic Q. Yes, it would be a company. 12 12 regulations? My question would be: Have you ever 13 13 been hired by a company who would -- who makes the A. No. 14 product --Have you ever been designated as an Q. 15 A. expert to talk about pharmaceutical, medical Okay. device, or over-the-counter regulations? 16 Q. -- the product I'm talking about, to 17 No, but I don't do much expert consult with regard to that particular product, and my last question was a prescription drug? 18 witness work. 19 19 I understand now. Is this the only legal case you're 20 20 currently consulting on? O. Have you ever been hired by a 21 A. Yes. 21 company to consult with regard to a medical device 22 they are manufacturing? Q. How many times have you given a 23 23 deposition? A. No. 24 24 Q. Have you ever been hired by a A. Only -- only once. Page 41 Page 39 1 company to consult with regard to an Q. When was that? 2 <sup>2</sup> over-the-counter product that they are That was, roughly, 10 years ago in A. <sup>3</sup> the antitrust litigation I mentioned. An manufacturing? <sup>4</sup> excellent assistant section chief from the FTC No. <sup>5</sup> took my deposition in Austin, Texas on that case. Qualification, though I would not be <sup>6</sup> able to remember the details, is I provide Q. Who were the hospitals involved? <sup>7</sup> informal advice many times to people unpaid with It was two hospitals in Rockford, and they have changed their names enough so that <sup>8</sup> no documentation, often my own students, sometimes <sup>9</sup> I, frankly, can't remember. I would have to look <sup>9</sup> students elsewhere in the university who are doing 10 at something to refresh my recollection. collaborative startup work. And they have 11 Okay. Have you ever taken a something that they are interested in and has a deposition as a lawyer? 12 health policy, health reimbursement, health law 13 type connection, and they reach out, and I am very A. No. 14 Have you ever testified in court? generous with my -- my unpaid time. Q. 15 15 I've -- I've never testified as a So it's quite possible that <sup>16</sup> witness in court. I've served on juries and have something meeting these descriptions happened 17 voir dire. during those contacts over the years. 18 18 Have you ever been hired by a Have you ever consulted with a Q. company to consult with regard to a cosmetic consumer product company on any issue? 20 ingredient? 20 DR. THOMPSON: Object to form. 21 21 A. THE WITNESS: Have I ever No. 22 22 consulted. Again, for hire? No. Have you ever been hired by a 23 BY MR. HEGARTY: company to consult regarding a cosmetic product?

24

No.

A.

24

Has any cosmetic, pharmaceutical,

Page 44 <sup>1</sup> company or over-the-counter company ever hired you practice that would be relevant to 2 <sup>2</sup> as a consultant for any issue? cosmetic companies. Would you repeat that question? A. BY MR. HEGARTY: 4 4 O. You have no personal experience on Has any cosmetic, pharmaceutical, or working within a cosmetic company? <sup>6</sup> over-the-counter product company ever hired you to A. Correct. <sup>7</sup> assist them with anything? Have you ever assisted a company in Q. Again, not for hire. Not for hire. developing a cosmetic? <sup>9</sup> I have a wide circle of acquaintance. I do A. 10 speaking for many organizations, including 10 O. Have you ever assisted a company in 11 conferences that may have been funded by testing a cosmetic? 12 pharmaceutical companies over the years, but 12 No. A. 13 nobody has hired me individually for consulting 13 O. Have you ever assisted a company in <sup>14</sup> advice. manufacturing a cosmetic product? 15 Have you ever been -- strike that. 15 Α. 16 So you have never been employed by a 16 O. Have you ever assisted a company in 17 pharmaceutical, medical device, or consumer marketing a cosmetic? product company, correct? 18 Personally, no. My mom was involved 19 Correct. in some cosmetic advertising decades ago. 20 Have you ever been involved in a You've never worked for Johnson & O. <sup>21</sup> Johnson, correct? company's analysis of safety data regarding a 22 cosmetic? A. No. 23 23 You've never worked for any Johnson Q. A. 24 <sup>24</sup> & Johnson company, right? Q. Have you ever advised a company Page 45 Page 43 I have had a lot of contact over the <sup>1</sup> about the testing needed to show the safety of a <sup>2</sup> years with the Robert Wood Johnson Foundation, and cosmetic? <sup>3</sup> I've been a recipient of at least one of their 3 A. No. <sup>4</sup> grants, but I have not -- I haven't been hired by O. Have you ever assisted a company in <sup>5</sup> a corporate entity having anything to do with communicating with the FDA about a cosmetic? <sup>6</sup> Johnson & Johnson. A. No. Does Johnson & Johnson still --Q. Q. Have you ever drafted a warning for 8 strike that. 8 a cosmetic? 9 Does Johnson & Johnson still sell A. No. <sup>10</sup> Shower to Shower? 10 Have you ever -- have you ever 11 I don't know. advised a cosmetic company about the need for a You are not an expert in how a 12 Q. warning on a cosmetic? 13 cosmetic company operates, correct? 13 A. 14 14 DR. THOMPSON: Object to form. Q. Have you ever worked with a company 15 THE WITNESS: I am an expert on developing a warning for a cosmetic? 16 in how a lot of companies operate. What 16 A. 17 17 is particular to a cosmetic company I O. Have you ever drafted -- strike 18 couldn't say, but I have corporate law that. I asked you that. 19 19 practice experience. I have corporate Have you ever communicated with a 20 law teaching experience. I have company about the cosmetic regulations? 21 21 securities law teaching experience. A. No.

22

Golkow Litigation Services

And my mother spent her career

doing fashion advertising. So I suspect

I know a fair amount about corporate

22

23

24

Have you ever been employed by a

DR. THOMPSON: Object to form.

company in any capacity?

Page 48 1 THE WITNESS: I'm not exactly <sup>1</sup> administrative agency, correct. sure what you're asking, I mean. You've never communicated with <sup>3</sup> BY MR. HEGARTY: anyone at FDA regarding a cosmetic, correct? 4 It's as broad as it can be. Α. Correct. 5 Have you ever worked for a company? Q. You've never served on any FDA 6 I mean, a law firm is a -- is a committees, correct? company. So yes. (Laugh). Ever served on an FDA committee. A. Have you ever worked for a company Correct. outside of O'Melveny? Q. FDA has never contacted you about a 10 I worked -- I was a summer associate cosmetic, correct? 11 at Davis Polk and Wardwell. (Laugh). Α. Correct. 12 12 Fair enough. Q. You've never worked with Health 13 You've never worked for FDA, Canada, correct? 14 14 A. correct? Correct. 15 15 Correct. Oh, and, again, not a Q. You've never worked with any foreign A. company, but I -- I was a full-time federal <sup>16</sup> regulatory agency, correct? A. It's a good question. employee briefly in 1993 with the White House. 18 18 I have been an invited speaker and Q. But you never worked for FDA, 19 conference participant in, you know, several correct? countries that involved health policy agencies, 20 Α. Correct. 21 <sup>21</sup> health insurance agencies. I have had many Q. Have you ever worked for a <sup>22</sup> discussions over the years. I haven't worked on governmental agency? 23 discrete projects with them in a sustained way. Again I worked --24 DR. THOMPSON: Object to form. You're not an expert in Canadian Q. Page 47 Page 49 1 THE WITNESS: I worked in the <sup>1</sup> cosmetic regulations, correct? 2 White House in 1993 as a full-time DR. THOMPSON: Object to form. 3 employee and, you know, with a clearance THE WITNESS: Correct. 4 and with a lot of connections with the <sup>4</sup> BY MR. HEGARTY: 5 federal government. You've never communicated directly 6 with Health Canada, correct? I work extensively with state 7 governments on various issues from time A. Correct. 8 to time. I provide informal advice to O. You cannot cite to me a single 9 people in federal health agencies, in cosmetic -- you cannot cite to me a single 10 self-regulatory organizations. It's what Canadian cosmetic regulation, can you? 11 I do. I mean, this is a career of this. DR. THOMPSON: Object to form. 12 <sup>12</sup> BY MR. HEGARTY: THE WITNESS: Can I cite? 13 13 Understood. Let me ask it a No. But my habit is always to look 14 14 different way. things up. So I don't cite very much. 15 15 You've never been employed by a Have I now read a little about Canadian 16 governmental agency, correct? cosmetic regulation? Yes, but I don't --17 17 DR. THOMPSON: Object to form. I don't know chapter and verse. 18 THE WITNESS: Other than the BY MR. HEGARTY: 19 19 Have you ever read the Canadian White House, no. 20 20 cosmetic regulations? BY MR. HEGARTY: 21 21 But you know government being the A. No. 22 <sup>22</sup> job you had at the White House was not with an Have you ever referenced in any <sup>23</sup> agency, right? <sup>23</sup> publication of yours a Canadian regulation 24 <sup>24</sup> regarding cosmetics? It was not with a federal

Page 50 Page 52 1 Regarding cosmetics? No. A. <sup>1</sup> FSAR for talc, correct? 2 Have you ever referenced in any O. Again, I am not great with acronyms. publication of yours a finding by Health Canada? <sup>3</sup> If you want to show me? 4 DR. THOMPSON: Object to form. O. Sure. 5 THE WITNESS: I don't believe It may be in my binder, but I just A. 6 want to make sure I'm looking at the right thing. SO. <sup>7</sup> BY MR. HEGARTY: MR. HEGARTY: I'll show you a 8 Do you claim to be an expert in copy of it, and I'll mark as an exhibit. 9 Health Canada's risk assessment process? (Document marked for 10 DR. THOMPSON: Object to form. 10 identification as Sage Exhibit 2.) 11 BY MR. HEGARTY: THE WITNESS: I have read 12 their weight of evidence documents, which 12 I'm marking as Exhibit No. 2 the 13 are compatible with documents elsewhere, screening assessment by --14 14 A. and I've worked on harmonization efforts Yeah. 15 15 involving drug approval regulations Q. -- Health Canada for talc that's 16 involving many countries, including the dated April 21 -- April 2021. 17 17 Canadian system, but I don't know what And you have read this document, 18 more than that I could -- I could offer. 18 correct? 19 BY MR. HEGARTY: 19 Yes, I have -- I have reviewed this 20 Well, with regard to the Canadian document, which means reading much of it. Did I <sup>21</sup> risk assessment process, the only document you've read every word? Probably not. <sup>22</sup> read about that is the 2001 Canadian FSAR, And you mentioned before that you 23 correct? <sup>23</sup> had not read it prior to being contacted by 24 <sup>24</sup> counsel for plaintiffs in this case? DR. THOMPSON: Object to form. Page 51 Page 53 1 THE WITNESS: I would have to A. That's correct. 2 2 look at what exactly the document you --Do you know who wrote this document? Q. 3 3 I've read -- I thought it was a A. No. 4 considerably more recent document on O. Do you know who was involved in 5 <sup>5</sup> analyzing the data in putting this document weight of evidence explaining how they do 6 6 together? their risk assessment, what evidence, you 7 know, is -- is incorporated, what might As individuals, no. I would assume 8 not be. that Health Canada is at governmental level 9 responsible for the assessments they issue. I'm familiar with risk 10 10 Do you know the expertise of anyone assessment documents for many contexts, 11 whether European precautionary principle 11 involved in putting Exhibit No. 2 together? 12 12 documents or, you know, U.S. A. I can make inferences, but, no. 13 13 Did you submit any material as part cost-effectiveness, cost-benefit 14 executive order type economic analysis of this Health Canada process that led to Exhibit 15 No. 2? regulation documents. I don't know the 16 16 ins and outs of them. I have a good A. 17 17 familiarity with how the system works. O. Did you or have you communicated <sup>18</sup> BY MR. HEGARTY: with Health Canada regarding this assessment? 19 19 Have you read anything about Health A. Canada's risk assessment as it relates to talc 20 Q. Did you know Health Canada was even <sup>21</sup> doing an assessment about talc prior to being <sup>21</sup> before being contacted by plaintiffs' counsel in <sup>22</sup> this case? 22 contacted by plaintiffs' counsel in this case? 23 23 A. A. No. 24 24 O. Q. And you have read the Health Canada Do you recall from reading Exhibit

Page 56 <sup>1</sup> No. 2 that it references as part of its reliance <sup>1</sup> plaintiff experts? 2 <sup>2</sup> materials expert reports from U.S. litigation? I didn't know that but --I don't recall anything about the 3 O. Okay. <sup>4</sup> references in this report. A. -- I'll take your word for it. Well, if you turn to, for example, Can you cite for me any time FDA has O. <sup>6</sup> page 55 of this report that we marked as Exhibit cited to litigation expert reports in publishing a <sup>7</sup> No. 2 -safety finding? A. DR. THOMPSON: Object to form. Uh-huh. 9 9 -- and four lines up from the bottom THE WITNESS: That is exactly Q. the sort of question I would research <sup>10</sup> of that page, there's a reference -- let me --10 <sup>11</sup> that's not the right one. I'll find the one I 11 before offering a view on. <sup>12</sup> want to reference you to. 12 BY MR. HEGARTY: 13 Okay. If you go to page 62. I'm 13 Do you know if Health Canada has <sup>14</sup> sorry. Two lines up from the bottom, there's a ever in any safety assessment cited expert reports <sup>15</sup> reference to a Rule 26 expert report of Judith from U.S. litigation? <sup>16</sup> Wolf from 2018. 16 DR. THOMPSON: Object to form. 17 17 Do you see that? THE WITNESS: I'm not aware 18 18 A. I do. of that, but this is the research 19 Had you noted that before I pointed 19 process. I don't give casual reads on that out to you right now? 20 20 complicated facts. I look things up. 21 <sup>21</sup> BY MR. HEGARTY: A. No. 22 The one you referenced earlier on In any published article of yours, page 55, the McTiernan, reminded me that I did <sup>23</sup> have you ever cited an expert report from a <sup>24</sup> litigation? <sup>24</sup> review Congressional testimony as part of learning Page 55 Page 57 <sup>1</sup> about these issues --Not to my -- not to my knowledge, 2 <sup>2</sup> but it's possible. Q. Okav. 3 -- and formulating my opinions. Do you -- don't you find it unusual A. And if you go over to page 59, do <sup>4</sup> that a governmental agency would cite to a <sup>5</sup> you see about five lines down from the top and <sup>5</sup> litigation report as part of its reliance <sup>6</sup> about another five lines down, there's a reference material? <sup>7</sup> to an expert report by Jack Siemiatycki and a Α. I don't find --8 <sup>8</sup> reference to an expert report by Rebecca DR. THOMPSON: Object to form. 9 <sup>9</sup> Smith-Bindman? THE WITNESS: I don't find it 10 10 in the least unusual. One takes Do you see that? 11 11 Yes. information where one gets it. One A. 12 12 O. Do you see that those reports are in weighs its importance, its reliability. 13 <sup>13</sup> the same case in which your expert report was If I were -- if I were <sup>14</sup> filed, the United States District Court for the 14 advising a risk assessment body, I would <sup>15</sup> District of New Jersey MDL? 15 not put blanket exclusions on what it 16 16 Yes. I also see one in between the considers. 17 two. Actually, I see a couple including those 17 BY MR. HEGARTY: <sup>18</sup> there. 18 Q. You're familiar with IARC? 19 19 O. Yes. Α. Briefly, yes. 20 Dr. Singh. You see that? 20 Okay. Did you have any awareness of 21 Yes. IARC prior to being contacted by plaintiffs' Α. 22 22 And a Dr. Ellen Blair Smith? counsel in this case? O. 23 23 A. I'd seen --A. 24 24 O. You understand that those are all DR. THOMPSON: Object to form.

Page 60 1 1 articles that are now either published or THE WITNESS: I had seen the 2 2 in the works that weren't listed before. acronym. I knew there was such a body. 3 3 I hadn't read any of their specific MR. HEGARTY: If you could at 4 4 assessments. a break get us a copy -- get me a copy of 5 5 that, I would appreciate that. And I'll MR. HEGARTY: Mark as Exhibit 6 6 No. 3 a copy of the curriculum vitae of come back and just mark that as an 7 yours that we were provided in this 7 exhibit. 8 litigation. BY MR. HEGARTY: 9 Dr. Sage, do you understand that (Document marked for 10 <sup>10</sup> we're here today to take your deposition in the identification as Sage Exhibit 3.) 11 <sup>11</sup> case of In re: Johnson & Johnson Talc Litigation BY MR. HEGARTY: 12 Would you look at that document and <sup>12</sup> MDL, correct? <sup>13</sup> tell me whether this is your current curriculum 13 A. Yes. 14 vitae. Q. Who are the Johnson & Johnson 15 15 (Reviews document.) companies in this case? Α. 16 This is not the most recent version. 16 Again, I have not reviewed the case <sup>17</sup> I think I was asked to provide an update that <sup>17</sup> file in a litigation posture. included the GW visit, which is how I'm judging My understanding is that Johnson & 19 it --<sup>19</sup> Johnson's consumer subsidiary is the focal 20 <sup>20</sup> defendant. I don't recall whether the Johnson & Q. Okay. 21 <sup>21</sup> Johnson parent is also named. What little I know A. -- and this doesn't include that. 22 Did you bring a copy of your updated <sup>22</sup> of litigation would suggest that many parties are O. 23 <sup>23</sup> named. curriculum vitae? 24 24 You did mention the consumer A. Yes. Q. Page 59 Page 61 1 <sup>1</sup> company. There's Johnson & Johnson Consumer, Inc. O. Do you have it with you? 2 Yes, I think -- well, I think -- let Do you know when that company came A. <sup>3</sup> me see. I definitely do. Let me see what... <sup>3</sup> into existence? 4 MR. HEGARTY: Well, we can A. No. 5 come back. Can I get a copy of that when Q. Did you break down for purposes of 6 we have a break if you don't have it? <sup>6</sup> your report any analysis looking at the activities 7 DR. THOMPSON: I believe <sup>7</sup> between Johnson & Johnson and Johnson & Johnson 8 Consumer, Inc.? that --9 9 DR. THOMPSON: Object to form. MS. PARFITT: I thought that 10 10 THE WITNESS: I did in -- in was given to you. 11 11 DR. THOMPSON: -- was given to my report. I was very interested in how 12 12 you in the production but... the Johnson & Johnson companies were 13 13 organized in terms of what regulated MR. HEGARTY: Okay. The one I 14 14 products they produced, not just had brought with me that I had asked 15 15 folks to give me is the one I marked as cosmetics, but drugs, medical devices, 16 16 and the like and so, you know, I at a Exhibit No. 3. 17 17 THE WITNESS: Yeah. So -high level of generality reviewed the 18 18 MS. PARFITT: We can check and organizations. 19 19 substitute it. And I think at some point, 20 20 there is a paragraph here that points out MR. HEGARTY: Okay. 21 DR. THOMPSON: But I believe 21 Johnson & Johnson's umbrella expertise 22 22 the only change was his current position and which subsidiaries have which 23 23 divisions. All of which I thought was at GW so ... 24 24 interesting as it related to their THE WITNESS: And a couple of

Page 64 1 regulatory experience and obligations. DR. THOMPSON: And I would 2 <sup>2</sup> BY MR. HEGARTY: claim that those e-mails are privileged But in terms of the analysis that 3 4 <sup>4</sup> you prepared across your report, did you break MR. HEGARTY: I understand. <sup>5</sup> down the analysis as between the Johnson & Johnson DR. THOMPSON: -- a discussion <sup>6</sup> and Johnson & Johnson Consumer, Inc. companies? 6 of serving as an expert. DR. THOMPSON: Object to form. MR. HEGARTY: Understood. 8 THE WITNESS: No, I don't have BY MR. HEGARTY: 9 the specific details to explain that When was it that you agreed to serve 10 functionally, and as you well know in as an expert witness in relation to the first 11 contact? terms of legal accountability, the 12 12 functional assignment and legal A. Within a month. 13 13 accountability are not always the same. O. Apart from anything that you were 14 BY MR. HEGARTY: told by the attorneys during your communications, 15 do you know how they came to contact you? When were you first contacted about serving as an expert in this case? 16 DR. THOMPSON: Object to form. 17 Probably sometime in May of 2021. 17 BY MR. HEGARTY: 18 18 Q. Who contacted you? How Ms. Thompson -- Dr. Thompson 19 Dr. Margaret Thompson. came to contact you? A. 20 How was this contact made? 20 A. No. O. 21 21 Possibly e-mail, possibly telephone, Q. Do you have any social or business <sup>22</sup> relationship to Dr. Thompson? <sup>22</sup> possibly incidental to a general catch-up conversation. Yes. Dr. Thompson is one of my 24 <sup>24</sup> former law students at the University of Texas, Q. Do you recall getting e-mails from Page 63 Page 65 <sup>1</sup> and I taught her in more than one class and she <sup>1</sup> Ms. Thompson -- Dr. Thompson prior to --2 Thank you. was a great student. 3 Q. -- about potentially serving as an Q. What years did you teach her at the <sup>4</sup> expert witness before you agreed to serve as an 4 law school? <sup>5</sup> expert? I would have forgotten exactly what years, but I was reminded that I think it was 2004 A. I'm sure there are e-mails that <sup>7</sup> discuss it in some -- in some degree because I or thereabouts. So probably 2004/2005 or so. <sup>8</sup> don't solicit expert witness work, and it was Have you maintained any type of <sup>9</sup> important to me to understand both the social relationship with Dr. Thompson since you <sup>10</sup> relationship between my regulatory expertise and taught her in law school? <sup>11</sup> this matter and, you know, where my analysis was DR. THOMPSON: Object to form. 12 <sup>12</sup> likely to lead before I would agree to become an THE WITNESS: I've maintained 13 13 expert witness. the sorts of relationship I would have 14 14 Q. Do you still maintain those e-mails? with former students and, you know, 15 15 A. because Dr. Thompson and my family have I'm sure they exist, as all e-mails 16 exist. 16 moved in similar social circles in Austin 17 17 MR. HEGARTY: Well, we would during this time, we will run into each 18 18 ask you to retain those e-mails, and we other from time to time. 19 19 BY MR. HEGARTY: will make a request for a copy of any 20 e-mails that were generated prior to Dr. 20 Would you -- would you call 21 <sup>21</sup> Dr. Thompson a friend apart from your work on this Sage agreeing to serve as an expert 22 22 case? witness. 23 23 DR. THOMPSON: And -- sorry. A. Yes, definitely. 24 24 MR. HEGARTY: Go ahead. Q. Had you known any of the other

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- lawyers for the plaintiffs in which you have
   worked on on this case prior to your working with
- <sup>3</sup> them?
- <sup>4</sup> A. No. Since you said for the
- plaintiffs, that would exclude John Beisner.
- 6 O. Correct.
- <sup>7</sup> Had you had any working relationship
- <sup>8</sup> with Dr. Thompson prior to her contacting you
- <sup>9</sup> about potentially serving as an expert in this <sup>10</sup> case?
- A. We had had informal conversations
- <sup>12</sup> over the years about various things of the sorts
- <sup>13</sup> that I will routinely have with my former
- <sup>14</sup> students.
- Q. Give me an example.
- A. She would be working on vaginal mesh
- <sup>17</sup> litigation, and we would have a discussion of
- <sup>18</sup> vaginal mesh.
- <sup>19</sup> Q. In what sense of a discussion would
- 20 you have?
- A. I can't recall.
- Q. Okay. Does your wife have a social
- <sup>23</sup> relationship with Dr. Thompson?
- A. Former wife. We're divorced.

A. Yes. She had some involvement in

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- <sup>2</sup> the first campaign. I don't remember exactly for
- <sup>3</sup> how long.
  - Q. When was that involvement?
- A. I don't exactly recall. She -- she
- <sup>6</sup> helped Karen with some of the earliest fundraising
- <sup>7</sup> activities. I don't know the details or don't
- remember them.
- <sup>9</sup> Q. This would have been at a time that <sup>10</sup> you were still married, correct?
- 11 A. Yes, this would have been in 2010.
- Q. Do you know Dr. Ellen Smith?
- <sup>13</sup> A. I'm sorry. Ellen with an E?
- <sup>14</sup> O. Yes.
- A. Common name, but I don't think I do.
- Q. Do you know her husband, Dr. Alan
- <sup>17</sup> Campion?
- A. Also a name I think I have heard;
- <sup>19</sup> but, no, not personally.
- Q. Do you know Thomas Dydek?
- A. So Dydek is -- is Dr. Thompson's --
- <sup>22</sup> one of Dr. Thompson's sons' names, and I taught
- <sup>23</sup> one of Dr. Thompson's sons at Harvard Law School.
- <sup>24</sup> They're actually the only mother/son combination I
- Page 67
- Page
- Q. What's her name?
- <sup>2</sup> A. Karen Sage.
- <sup>3</sup> Q. She's a judge, correct?
- <sup>4</sup> A. Correct.
- <sup>5</sup> Q. Does Judge Sage have a social
- <sup>6</sup> relationship to your knowledge with Dr. Thompson?
- <sup>7</sup> A. Yes.
- <sup>8</sup> Q. Has she had any working relationship
- <sup>9</sup> with Dr. Thompson?
- A. Not to my knowledge.
- Q. Has Dr. Thompson or her firm ever
- donated to your wife's campaign?
- DR. THOMPSON: Object to form.
- 14 THE WITNESS: I don't know
- that for a fact. I would imagine that
- Dr. Thompson did donate to -- to my
- former wife's first campaign, but I have
- no recollection of specifics, and I
- certainly know nothing about subsequent
- campaigns.
- 21 BY MR. HEGARTY:
- Q. Do you know if Dr. Thompson has
- <sup>23</sup> had -- ever had any involvement in any of your
- <sup>24</sup> wife's political campaigns?

- <sup>1</sup> recall teaching in my career.
  - Q. Do you know if any attorney for the
- <sup>3</sup> plaintiffs in this case besides perhaps
- <sup>4</sup> Dr. Thompson ever donated any money to your wife's
- campaign?
- A. I have no knowledge of that.
- <sup>7</sup> Q. Prior to being -- to agreeing to
- 8 serve as an expert witness in this litigation, did
- <sup>9</sup> attorneys for plaintiff tell you anything about
- <sup>10</sup> the litigation?

15

- 11 A. Yeah.
- DR. THOMPSON: Object to form.
- THE WITNESS: Well, yes.
- 14 BY MR. HEGARTY:
  - Q. What did they tell you?
- DR. THOMPSON: And I'm going
- to instruct you not to answer what we
- to histract you not to answer what told you about the litigation.
- 19 BY MR. HEGARTY:
- Q. Okay. Prior to agreeing to serve as
- <sup>21</sup> an expert witness, did counsel for plaintiffs show
- <sup>22</sup> you any documents?
- A. Yes, in that I think I specifically
- 24 asked for the most recent court ruling, one of the

<sup>1</sup> Daubert causation type rulings. I thought that

- <sup>2</sup> would give me some of the -- the background I
- <sup>3</sup> needed to evaluate the overall litigation and
- <sup>4</sup> whether my particular expertise would be relevant
- <sup>5</sup> and appropriate.
- I want to make this clear if it's Q. <sup>7</sup> not.
- Was there a time before you had agreed -- was there a time between the first
- 10 contact that you had with Dr. Thompson and you <sup>11</sup> actually agreeing to serve as an expert witness?
- 12 Absolutely. There was a long period
- <sup>13</sup> of time that I had to understand how my expertise
- <sup>14</sup> fit with this litigation, understand what I
- 15 thought about the defendants' conduct and
- <sup>16</sup> compliance or noncompliance with regulation.
- <sup>17</sup> Yeah, I thought very seriously about it.
- 18 O. And during that period of time, did
- you -- did you -- let me back up.
- Did you ultimately bill any of the
- <sup>21</sup> time you spent doing that to the plaintiffs'
- <sup>22</sup> counsel after agreeing to serve as an expert
- <sup>23</sup> witness?

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Certainly not. A.

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DR. THOMPSON: Object to form. THE WITNESS: Certainly not.

I, frankly, bill minimally for these things.

<sup>5</sup> BY MR. HEGARTY:

And during this period of time, did <sup>7</sup> you consider yourself as being a retained expert for the plaintiffs?

> DR. THOMPSON: Object to form. THE WITNESS: I considered myself being asked to consider being an expert. I was -- this was in the context of being asked to serve as an expert.

Did I consider myself already aligned with the plaintiffs' position? Certainly not. I was making an independent decision.

BY MR. HEGARTY:

19 You mentioned that you requested the 20 Daubert ruling.

21 Had you heard of the Daubert ruling before being contacted by plaintiffs' counsel?

- Before being contacted by
- <sup>24</sup> Dr. Thompson, no. But in part of those

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- <sup>1</sup> discussions, she referred to what had happened
- <sup>2</sup> with the case recently, including the Daubert
- <sup>3</sup> ruling, and as you might imagine given my career,
- <sup>4</sup> I like to read things and see for myself, and so I
- wanted that document.
- Had you heard of lawsuits involving <sup>7</sup> talc and ovarian cancer before being contacted by
  - Dr. Thompson? Yeah, certainly.
- 10 O. And where had you heard of those 11 lawsuits?
- 12 A. In my, you know, daily and weekly <sup>13</sup> health law litigation, professional
- responsibility, tort liability, e-mail and news
- <sup>15</sup> feeds, and the things I read professionally on a routine basis.
- 17 O. And how much had you read, whether you do it by volume or time, spent about cases or litigation involving talcum powder use and ovarian
- cancer before being contacted by Dr. Thompson? 21 It had been infrequent. I would --
- <sup>22</sup> I would, you know, see this type of multidistrict
- <sup>23</sup> or multi-plaintiff litigation referred to the same
- <sup>24</sup> way I'd seen other cases referred to. It didn't

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- <sup>1</sup> particularly attract my attention, but I certainly
- <sup>2</sup> would read it. It was important.
- 3 Q. And you mentioned the Daubert <sup>4</sup> ruling.
  - What other documents did you review
- <sup>6</sup> between the time you were contacted by
- <sup>7</sup> Dr. Thompson and when you were -- you agreed to
- <sup>8</sup> serve as an expert as you were doing this
- <sup>9</sup> evaluation yourself?
- 10 That's the -- that's the document
- that the plaintiffs' lawyers provided that I
- remember at the moment. I did not ask for or
- receive any corporate or confidential documents.
- And I think what I did with respect to the talc
- 15 litigation was more of the Google search of what
- might have happened recently and what I would see.

And then I thought it worth

- <sup>18</sup> reviewing the basics of -- of cosmetics regulation
- again to refresh my understanding of how the
- cosmetics piece fit in the larger FDA scheme. 21 And prior to being contacted by
- <sup>22</sup> counsel for plaintiffs, Dr. Thompson, had you
- <sup>23</sup> formed any opinions about with regard to
- <sup>24</sup> litigation involving talcum powder use and

Page 21 of 110 Page 74 Page 76 <sup>1</sup> allegations of ovarian cancer? <sup>1</sup> materials, additional sort of building my 2 <sup>2</sup> knowledge of the facts and circumstances. A. No. 3 Q. You were ultimately hired as an Are you able to break down the hours <sup>4</sup> expert witness in this case; is that correct? <sup>4</sup> that you have spent since your last invoice on how much time you spent preparing for this deposition? Correct. The lawyers for the plaintiffs paid Not off the top of my head. I do Q. <sup>7</sup> you to review materials and then offer opinions, <sup>7</sup> keep, you know, notes of -- of hours per day in a right? general sense of what I'm spending them on. So, yes, I could -- I could break that out. A. Correct. 10 10 Q. Those opinions were ultimately set Do you have -out in your July 2, 2020 -- 2021 MDL report; is 11 I would think it should be the 12 that correct? <sup>12</sup> majority of the 40 hours because this was the 13 13 focal point, and we've rescheduled a little and A. Correct. 14 it's, you know. And that is the report we marked as 15 15 Exhibit No. 1; is that right? Have you spoken with any of your 16 I'm sorry, not Exhibit No. 1. Let colleagues at work about your work on this case? 17 17 me back up. I don't think I marked it. A. 18 18 I don't think you marked it yet Q. Have you told any of them -- any of Α. the colleagues that you have at work -- about your either but I --20 opinions in this case? Yes. Let me go ahead and mark that. Q. 21 21 I have a copy of it in front of me. A. No. 22 22 MR. HEGARTY: So let me mark O. Have you told any of the 23 your July 2, 2021 MDL report as Exhibit gynecologists and gynecologic oncologists at the 24 <sup>24</sup> University of Texas Dale Medical School of your No. 4. Page 75 Page 77 <sup>1</sup> opinions? (Document marked for 2 2 identification as Sage Exhibit 4.) A. <sup>3</sup> BY MR. HEGARTY: O. How about those same doctors at And would you confirm for me that <sup>4</sup> McGovern Medical School? Have you talked to <sup>5</sup> Exhibit No. 4 is a copy of your July 2, 2021 them --<sup>6</sup> expert report? A. Which is --A. Yes, confirmed. -- about your opinions? Q. And your invoice that we marked I'm sorry. You would have to remind previously sets out the hours you spent reviewing me what McGovern Medical School is. <sup>10</sup> materials in connection with your work to prepare 10 0. Okay. You don't know what that is? 11 the report, correct? There -- there have been McGovern 12 A. Yes. names involved in some of the University of Texas 13 13

It also sets out the time you spent

drafting the report, right? 14

15 A. Yes.

16 And with regard to this deposition

that we're here today to do, how many -- how much

time did you spend preparing for this deposition?

19 Again, I think I -- when you asked

<sup>20</sup> earlier about accrued but unbilled time, I said I

<sup>21</sup> think there's about 40 hours, not including today,

<sup>22</sup> that have accrued between the filing of this

<sup>23</sup> report and now. That wasn't all preparation for

<sup>24</sup> the deposition. It was additional review of

areas, but I don't actually know.

Well, let me ask in a broader sense.

15 Have you spoken to any gynecologist or gynecologic oncologist at any UT healthcare

facilities about your opinions in this case?

A. No.

19 Have you told any doctors treating

patients for ovarian cancer about your opinions in

this case?

14

18

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A.

23 Q. Have you told anyone at FDA about <sup>24</sup> your opinions?

Page 78 Page 80 Not yet, but I'm -- I haven't seen <sup>1</sup> of this housekeeping matter. <sup>2</sup> people yet in DC, and should I see people, I will You brought some materials with you <sup>3</sup> be interested in discussing this with them. here today; is that correct? Yes. Do you currently have plans to A. <sup>5</sup> submit your report or otherwise communicate with 0. The notebook sitting in front of <sup>6</sup> FDA about your opinions in this case? 6 you? 7 I -- part of what I do routinely is Yes. A. <sup>8</sup> work with government agencies, with legislators Q. Is that a notebook you put together? <sup>9</sup> federal and state and, yes, I'm sufficiently 9 A. 10 concerned about some of the things that I've 10 Q. Who put it together? <sup>11</sup> reached conclusions about in connection with this 11 The plaintiffs' lawyer. Α. 12 <sup>12</sup> report that, yes, I intend to talk to people. Q. Did they put it together at your 13 I suspect I more like to talk --13 direction? 14 <sup>14</sup> more likely to talk to Congressional staffers than A. I asked them to provide me with <sup>15</sup> I am to FDA people because I think I'm more likely things that would be helpful, as I haven't been to be in contact with those people. deposed in years. 17 17 Have you communicated with anyone as O. Could you walk me through what's in <sup>18</sup> of today outside of plaintiffs' lawyers about your 18 the notebook? 19 report? 19 Certainly. 20 A. 20 There's -- there's the notices of No. 21 Q. Have you discussed this litigation <sup>21</sup> deposition. There's the report with attachments. <sup>22</sup> or your report with any other experts that have <sup>22</sup> My invoice was here. There's a separate copy of <sup>23</sup> been identified by the plaintiffs in the MDL case? 23 my CV, though I noticed it was also attached to 24 <sup>24</sup> the report. There's the FDA's response to the two A. No. Page 81 Page 79 <sup>1</sup> Citizen's Petitions from 2014. There's some IARC I'm very interested in what the <sup>2</sup> defense experts might say with respect to my <sup>2</sup> material. There's some Health Canada material, <sup>3</sup> opinions. So if those people exist, I'll look <sup>3</sup> and there's your client's submission to Health <sup>4</sup> forward to reading what they -- what they think. <sup>4</sup> Canada. And then there's a little loose material. MR. HEGARTY: I'm going to O. What is that loose material? 6 mark as exhibit number -- I guess, before A. The loose material is the casebook 7 <sup>7</sup> chapter on cosmetics that I cite in the report. I I do that, do you want to take a break at 8 this point? requested specifically the most recent Senate 9 MS. THOMPSON: I was just <sup>9</sup> version of the Personal Care Product Safety Act 10 <sup>10</sup> bill that's been introduced. thinking it's about time. 11 MR. HEGARTY: Yeah, let's take There's the NCI informal statements 12 <sup>12</sup> on talc and ovarian cancer and there's a small a break. 13 acronym glossary that I asked -- that I DR. THOMPSON: It's a good 14 specifically asked for just to refresh my memory spot. 15 about things like, you know, the Personal Care MR. HEGARTY: Yeah, it's a <sup>16</sup> Products Council and what things are called so 16 good spot. Let's go off the record. 17 (Recess: 9:21 a.m. that I remember. 18 18 9:35 a.m.). And then there's this FDA internal 19 <sup>19</sup> review from 1998 that actually talks about the MR. HEGARTY: We're back on 20 <sup>20</sup> inadequacies of the CIR and actually raises the record. <sup>21</sup> concerns about the safety of talc regarding 21 BY MR. HEGARTY: 22 <sup>22</sup> ovarian cancer. Doctor, when we broke, I was going 23 to show you a portion of your -- let me back up 23 Q. Can I see that document, please? <sup>24</sup> before I do that. I want to make sure I take care 24 A. Certainly.

Page 82 1 <sup>1</sup> underlying science because I actually am capable Q. It is a document Bates number <sup>2</sup> of reading the underlying science, and I wouldn't <sup>2</sup> PCPC058604 to 058654. <sup>3</sup> be comfortable with only having secondary sources Is this a document you've read? 4 <sup>4</sup> on the underlying science. A. Yes. 5 With regard to this document we're Q. And then you mentioned a list of looking at, Exhibit No. 5, did you prepare this? 6 acronyms. 7 Is that something the lawyers for No, this was --8 the plaintiffs prepared for you? Who prepared it? O. 9 At my request very specifically. Probably Brianne with the A. plaintiffs' lawyers. 10 MR. HEGARTY: Okay. Thank 10 11 11 And with regard to the materials vou. 12 I mark next as Exhibit 5 a <sup>12</sup> that are listed in Exhibit No. 5, do you know how 13 the plaintiffs' lawyers went about selecting these portion of your expert report. 14 materials to send to you? What their methodology (Document marked for 15 15 identification as Sage Exhibit 5.) was? 16 <sup>16</sup> BY MR. HEGARTY: DR. THOMPSON: Object to form. 17 17 And feel free to refer to that or go THE WITNESS: In many 18 to your expert report where that part is. instances, it was a specific request. I It is the document that you have or 19 requested a lot of the science. I <sup>20</sup> the part of your report that has "Literature" at 20 requested a lot of the historical <sup>21</sup> the top of it in the upper left-hand corner. 21 background for context for the science. 22 <sup>22</sup> Pages 1 through 18. I was interested in certain 23 And if you could look through that types -- certain of the deposition <sup>24</sup> document and tell me whether you have read all the 24 testimony. I was interested in Page 83 Page 85 <sup>1</sup> material that is listed in those pages. legislative action. 2 All the material that was in these I was very specifically 3 <sup>3</sup> pages was made available to me. I read word for interested in the defendants' responses <sup>4</sup> word certain items that I thought were relevant 4 in the defendants' case, and I repeatedly 5 <sup>5</sup> and important for my consideration. Other things asked when we're considering particular <sup>6</sup> I may have looked at part of. Other things I may 6 questions, you know, well, what would the <sup>7</sup> have looked at by title. defense say on this? 8 And when there were statements in my BY MR. HEGARTY: <sup>9</sup> report that required or benefited from having O. You did receive some materials from <sup>10</sup> cross-references to litigation documents, those the plaintiffs' counsel that you did not <sup>11</sup> would have been materials that plaintiffs' counsel specifically request; is that correct? 12 <sup>12</sup> supplied for the footnoting, and some of those I A. Yes. 13 13 would not have read. Do you know how as to those 14 You said made available to you, are materials the plaintiffs' lawyers went about <sup>15</sup> all the materials that are contained in Exhibit choosing what to send to you? <sup>16</sup> No. 5 sent to you by counsel for the plaintiffs? 16 No, I don't know. 17 17 There was a Dropbox account made Q. And with regard to the -- or let me

back up.

A.

Q.

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Golkow Litigation Services

<sup>24</sup> ask for those, and that included a lot of the

<sup>18</sup> available that I -- that I could access. Certain

<sup>19</sup> materials were also e-mailed to me. Usually

<sup>21</sup> came out of drafts through discussions.

22

<sup>20</sup> things that I had either specifically asked for or

<sup>23</sup> interested in in reviewing in detail. I tended to

I had certain things that I was very

Do you understand the materials that

we're looking at listed in Exhibit No. 5 include

Are you aware that there are

expert reports and some expert depositions.

Do you recall that?

Yes.

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 $^{\rm 1}\,$  hundreds more expert reports and depositions from

<sup>2</sup> the litigation, the MDL litigation, that are not

- <sup>3</sup> on this list of materials?
- <sup>4</sup> A. I would assume that. I don't know <sup>5</sup> that for a fact.
- Q. Do you understand that this list
   only includes two reports from defense experts,
   Dr. Weed and Dr. Anderson.
- Do you understand that?
- <sup>10</sup> A. I would have to go look through <sup>11</sup> this; but, yes, I will take your word for that.
- Q. Well, did you ask plaintiffs'
   counsel to give you all the defense expert reports
   and depositions?
- A. I did not ask for all of the
   plaintiffs' and I did not ask for all of the
   defense. I asked for documents that would express
   key aspects of the defense positions.
- 19 Q. Well, you --
- A. And I asked specifically for
   anything that might relate to -- to the regulatory
   analysis, of course.
- <sup>23</sup> Q. But you would agree that you have <sup>24</sup> not done a comprehensive analysis of the expert

are some that go into the science and not the
 regulatory issues, correct?

A. Yes. I reviewed some science and I
 was particularly interested in regulatory
 materials, especially deposition testimony, and I
 was particularly interested in marketing-related

<sup>7</sup> materials because that goes to the informational

- environment and the informational obligations of a
   cosmetics manufacturer.
- Q. But you did not request all the science reports and depositions of the defense expert witnesses, correct?
- A. That is correct. I requested
  specifically what might be considered the key
  scientific studies on both sides of the question,
  and I very emphatically requested both sides of
  the question.
- Q. Did you request the key scientific opinions to the reports and depositions of all the witnesses, regardless on what side they are on?
- A. I didn't request every opinion. I
  was more interested in the underlying published
  scientific literature, to the extent it existed,
  and deposition testimony that would supplement it

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Page 88

<sup>1</sup> reports and depositions in the MDL, correct?

DR. THOMPSON: Object to form.

THE WITNESS: I think I

considered everything I needed to

consider to formulate my opinions.

<sup>6</sup> BY MR. HEGARTY:

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Q. How do you know you considered
 everything you needed to consider if you don't
 know what others have said in reports and
 depositions that you don't have?
 DR. THOMPSON: Object to form.

THE WITNESS: If there's a set of regulatory opinions from defense experts, I would love to see them and I would be happy to take account of them in finalizing my views.

My -- my understanding was that -- having asked, was that there were not defense expert reports specific to regulation at this at this juncture. If that's wrong, I'd love to know.

22 BY MR. HEGARTY:

<sup>23</sup> Q. Well, you understand that the <sup>24</sup> reports and depositions included in Exhibit No. 5

where you couldn't actually assess the science
 from what had been published.

<sup>3</sup> Q. In your expert report, you actually <sup>4</sup> cite to a report by Drs. Longo and Rigler.

Do you recall that?

- A. I do recall that.
- Q. Do you recall that that's the only expert report that you specifically cite in the body of your written report?
- A. As -- as I recall, that is an expert report that relates to adulteration of talcum powder products with asbestos, and it was sufficiently important to highlight in the body of the report.
- Q. Do you intend to rely on any other expert report or deposition besides Drs. -- the report of Drs. Longo and Rigler cited in the body of your expert report?

A. I consider --

DR. THOMPSON: Object to form.
THE WITNESS: I consider
everything. Given the nature of my

regulatory expertise and the fundamental opinions that I'm expressing, I think

Page 90 Page 92 1 it's really a question of the totality of might -- might have. 2 <sup>2</sup> BY MR. HEGARTY: the evidence in front of me. 3 I don't think there's any My follow-up question to that, 4 single material that I rely on in <sup>4</sup> though, is: You agree that you did not consider 5 the sense if you're suggesting that my every reference in Exhibit No. 5 as part of your 6 opinions depend only on one particular opinions in this case? 7 A. I -report. 8 BY MR. HEGARTY: DR. THOMPSON: Object to form. 9 9 THE WITNESS: I considered O. Well, there what I want to try to the materials. Did I consider every <sup>10</sup> find out is if you see a distinction between what 10 11 you considered and what you relied upon. sentence of material that I did not read 12 12 I considered. every sentence of? Of course not. 13 <sup>13</sup> BY MR. HEGARTY: DR. THOMPSON: Object to form. 14 THE WITNESS: My -- it's been 14 And there are materials in this 15 15 an education to me to learn how these exhibit that you did not read at all, correct? 16 16 terms are used in this type of DR. THOMPSON: Object to form. 17 17 proceeding. THE WITNESS: There are 18 18 I think one expresses the fact materials in this exhibit that I would 19 19 of the matter and how I think about it is have looked at the title of, and that 20 20 that I request a lot of material. I'm perhaps when I had conversations with the 21 21 provided a lot of material. I consider plaintiffs' lawyers about what were the 22 22 everything that I'm provided. key scientific studies on each side, 23 23 I don't feel that any piece of didn't fall in that category; and, 24 24 my opinion is driven by reliance on one therefore, although they were available, Page 93 Page 91 1 or a small number of documents. no, I did not read them. 2 BY MR. HEGARTY: Where I tend to think about 3 3 the term "reliance" is that I'm not And you agree you cannot consider 4 <sup>4</sup> something for your opinions that you didn't read, formulating independent scientific 5 conclusions; and so if we're talking correct? 6 about scientific judgments, then I'm 6 DR. THOMPSON: Object to form. 7 7 relying on either the published THE WITNESS: I don't agree 8 literature or the opinions of the 8 with that. I mean, I consider universe 9 9 scientific experts for those opinions. of materials. Some things may or may not 10 <sup>10</sup> BY MR. HEGARTY: be relevant, and some things may or may 11 You mentioned, though, that you take not be duplicative. 12 <sup>12</sup> into account everything that you considered, but They're made available to me 13 you would agree, though, that with regard to and because they're made available to me, <sup>14</sup> Exhibit No. 5, you did not read all the materials 14 my understanding is they're disclosed to <sup>15</sup> in Exhibit No. 5, correct? 15 you, and that's the universe we're 16 16 DR. THOMPSON: Object to form. discussing. 17 THE WITNESS: I think you 17 BY MR. HEGARTY: 18 18 asked me this before, and I think I Do you know the names of the 19 plaintiffs in the cases selected for trial in the explained that things were made available 20 and I looked at everything and decided <sup>20</sup> MDL? 21 21 what needed to be read in what detail. A. I do not know them. So in the MDL, <sup>22</sup> I don't think I know them at all. 22 And I actually think I pursued 23 23 the detail and a lot more of the science Do you know anything about them,

than another nonscientific expert

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<sup>24</sup> where they live, what their diagnoses were, things

Page 94 Page 96 <sup>1</sup> like that? Q. When is the last time you practiced 2 law? A. I know that they -- I know that at <sup>3</sup> least some of them would have serous ovarian The last time I practiced law would <sup>4</sup> carcinomas. I don't know anything more about <sup>4</sup> have been when I was working at O'Melveny and <sup>5</sup> them. Myers. How do you know that some of them O. When was the last time you practiced Q. <sup>7</sup> had serous invasive carcinoma? <sup>7</sup> medicine? I didn't say "invasive." I just A. Again, the last time I practiced <sup>9</sup> said "ovarian," but just in the sense that I know <sup>9</sup> medicine as a -- as a functional manner last time 10 that that's the form of ovarian cancer that's most <sup>10</sup> I cared for a patient in a structured clinical <sup>11</sup> at issue in terms of causation. <sup>11</sup> environment would have been when I was a resident 12 Do you have any knowledge of each of <sup>12</sup> at Johns Hopkins. However, I do have an active a <sup>13</sup> the plaintiffs who have been selected for trial 13 Texas medical license, and I am legally entitled 14 use of baby powder? to practice medicine in Texas. 15 15 MR. HEGARTY: I'll mark as the Α. No, I do not. 16 16 Do you have any knowledge of any next exhibit, which is Exhibit No. 6, the 17 tissue analysis conducted for each of the notice for your deposition here today. 18 plaintiffs selected for trial in the MDL? (Document marked for 19 No, I do not. 19 identification as Sage Exhibit 6.) 20 20 BY MR. HEGARTY: As an expert in this case, you do 21 <sup>21</sup> not represent the University of Texas, correct? And, Dr. Sage, have you seen this Correct. document before right now? 23 23 O. You don't speak for the University I think I saw it briefly via e-mail. 24 <sup>24</sup> of Texas, correct? Q. Would you turn over to page 3. Page 97 Page 95 A. <sup>1</sup> Starting on page 3, there's a list of 18 Correct. 2 paragraphs that carry over to page 9. Q. You're not speaking in this case for 3 <sup>3</sup> any regulatory group or agency, correct? Do you see that --4 A. Correct. A. Yeah. 5 5 You're not speaking for any law or -- that list? Q. O. 6 legal group, correct? Have you read through those paragraphs before right now? I'm speaking for myself, expressing 8 my own opinions. (Laugh). A. No. 9 O. Right. Q. Is that something that we can have 10 you read at a break, and then I'll ask you some You're speaking in this case solely questions about it as opposed to taking time on for yourself, correct? 12 DR. THOMPSON: Object to form. the record to -- to read? 13 13 THE WITNESS: Yes. It's up to you, whichever is more 14 BY MR. HEGARTY: convenient. 15 15 And all the opinions in your report MR. HEGARTY: Is that okay are your subjective opinions, correct? 16 with you, Dr. Thompson? 17 17 DR. THOMPSON: Object to form. DR. THOMPSON: That's fine. 18 THE WITNESS: They're my BY MR. HEGARTY: 19 19 professional opinions. Okay. Would you put that aside and 20 BY MR. HEGARTY: 20 we'll come back to that document. 21 21 Okay. Are you licensed to practice A. Okay. O. <sup>22</sup> law? 22 With regard to the expert report

<sup>24</sup> California and District of Columbia bars.

I am an inactive member of the

<sup>23</sup> that you prepared, Exhibit No. 4, have you sent

<sup>24</sup> that report to anyone besides counsel for the

Page 100 <sup>1</sup> plaintiffs and, of course, them perhaps to the expressed, but these are the opinions. <sup>2</sup> defense counsel? <sup>2</sup> BY MR. HEGARTY: No. My assumption was that this was O. That's fair. <sup>4</sup> not material to be shared. But prior to coming in here today, you understood that your opinions and on what you Do you have any drafts of this <sup>6</sup> rely for those opinions was to be set out within <sup>6</sup> report? There's always versions that the four corners of your July 2, 2021 report? <sup>8</sup> constitute drafts in the way that documents are A. Yes. <sup>9</sup> evolved electronically these days, but there would DR. THOMPSON: Object to form. <sup>10</sup> be versions I'm sure. BY MR. HEGARTY: 11 11 So at least coming in here today, And the reason I ask it that way is O. <sup>12</sup> sometimes you'll have a report that then is <sup>12</sup> all the opinions that you intend to offer in this <sup>13</sup> drafted and is never changed -- it changes, but case are those set out in your report, correct? 14 <sup>14</sup> the original version doesn't exist. Correct. 15 15 Do you have any drafts that you DR. THOMPSON: Object to form. 16 think still exist? <sup>16</sup> BY MR. HEGARTY: 17 17 Of an earlier version? And, likewise, all the materials on 18 which you intend to rely coming in here today were Q. Version. 19 Again, I'm really not sure how to those referenced in your report, correct? <sup>20</sup> answer that. I, you know, I write hundreds of 20 DR. THOMPSON: Object to form. <sup>21</sup> things that end up published, and I don't know if 21 THE WITNESS: All the -- all 22 <sup>22</sup> I even know my method for writing stuff anymore. the materials that I considered in 23 <sup>23</sup> It just happens. generating the report are -- I don't know 24 24 The report we marked as Exhibit what I'm supposed to say, you know -- are Q. Page 99 Page 101 <sup>1</sup> No. 4 defines the scope of your testimony in this contained in the report or provided to 2 <sup>2</sup> case, correct? you as they're supposed to be provided. 3 3 I really don't know how this A. Correct. 4 4 DR. THOMPSON: Object to form. works well enough, and I haven't done 5 5 this before. So I'm not sure I THE WITNESS: The report 6 includes my opinions, and they're the 6 understand all the terminology. 7 opinions I would plan to offer. I'm, of course, as a lawyer, BY MR. HEGARTY: 8 8 you know, careful and want to comply with 9 all requirements. As a lawyer, you understand that <sup>10</sup> this report is supposed to be your testimony as if 10 BY MR. HEGARTY: <sup>11</sup> you're on the stand before a judge and a jury, With regard to the substance of your 12 right? <sup>12</sup> report, except where you have used quotations, is 13 A. 13 it your testimony that all the sentences in your Yes. 14 You understand that your opinions on report are your own words and not copied from <sup>15</sup> what you rely -- the opinions and what you rely 15 others? upon are supposed to be within the four corners of 16 A. 17 17 this document, right? DR. THOMPSON: Object to form. 18 18 DR. THOMPSON: Object to form. THE WITNESS: So to the best 19 19 THE WITNESS: I understand of my knowledge, everything in the report 20 that I might generate an opinion based on 20 that is not in quotation or could be 21 21 our conversation today. I understand understood as -- as an expression of 22 that you might provide me with additional 22 something in something that's immediately 23 23 material that would cause me to cited, that's all original work. 24 24 The same -- I do this report supplement or modify an opinion I've

Page 104 1 the same way I would do any other when, I cite and I'd be happy to share 2 2 writing, you know, which includes having them with you if you want but... 3 materials drawn from various sources, <sup>3</sup> BY MR. HEGARTY: 4 working with those, you know, rewriting Well, for purposes of your report, 5 whenever you did discuss, summarize, or paraphrase things, re-expressing things. 6 the work of others, did you include a cite to that There's -- what I can say with 7 confidence is, there's not a, you know, work by others? 8 there's not a sentence or a phrase in DR. THOMPSON: Object to form. 9 9 this report that I haven't had my THE WITNESS: I suspect not 10 10 author's fingerprints on. universally, but, again, that wouldn't be <sup>11</sup> BY MR. HEGARTY: 11 the standards that one would apply to a 12 12 So you know that as an author that lot of report writing. If you want my 13 13 the obligation is to properly cite material to personal standards for citation, I'll be which you are relying or referencing, correct? 14 happy to share them. 15 DR. THOMPSON: Object to form. 15 BY MR. HEGARTY: 16 THE WITNESS: I think I am 16 The report -- well, let me go back 17 17 to Exhibit No. B -- I'm sorry -- Exhibit No. 5. experienced with standards for 18 18 publication. This is the --19 BY MR. HEGARTY: 19 A. Yes. 20 20 -- list of literature, and if you And the obligations require that <sup>21</sup> when you discuss, summarize, or paraphrase others <sup>21</sup> look over at page 8, there starts a number of pages that include deposition and hearing 22 that you include a citation to those others' work, 23 <sup>23</sup> correct? transcripts. 24 24 DR. THOMPSON: Object to form. Do you see that? Page 103 Page 105 1 A. THE WITNESS: I think that 2 depends very much on the context and the O. Did you read all of the depositions 3 context in, say, an academic publication <sup>3</sup> and hearing transcripts listed there in their 4 <sup>4</sup> entirety? or a student dissertation might be 5 somewhat different than in an internal A. Of course not. I was astonished to 6 realize how long these depositions are. I did law firm memo, and the standards for 7 read several. citation that apply to an expert report 8 are not something I have much familiarity Q. Do you recall sitting today which 9 ones you read in their entirety? with, beyond the general standards I 10 10 I don't recall sitting here. I would apply to my work. 11 BY MR. HEGARTY: could tell you some familiar names such as the --12 But did you write your expert report I mean, I know I read in its entirety over the <sup>13</sup> in a method different than what you have written course of several deposition days the deposition published articles? <sup>14</sup> testimony of Kathleen Wille. I know I read some 15 <sup>15</sup> of, I think, a Susan Nicholson deposition. DR. THOMPSON: Object to form. 16 16 THE WITNESS: I wrote -- I I know I read Koberna, which had to 17 wrote it the same way I would write do with marketing. And I remember reading every 18 something, but the standards for word of a couple of the plaintiffs' experts, but 19 <sup>19</sup> that was early in my work on the case, and I don't citation, for example, vary -- vary 20 differently between, say, a law review really remember the details. 21 21 article and a medical journal publication If you look over at page 10 above 22 <sup>22</sup> the section Other Sources, there are some trial or health policy. There's no single 23 standard for what you cite and when. <sup>23</sup> transcripts from a case referred to as Ristesund 24 <sup>24</sup> versus Johnson & Johnson. I have my own standards for

Page 106 Page 108 1 Do you see that? <sup>1</sup> are listed in these pages? 2 2 I do. A. Certainly. A. 3 Did you read the transcripts from 3 O. Do you know of their methodology for <sup>4</sup> the Ristesund trial that are referenced in this how they selected those documents to send to you? 5 exhibit? DR. THOMPSON: Object to form. 6 THE WITNESS: Again, I'm --Things here were made available to <sup>7</sup> me. I -- I recall reading some PowerPoints in 7 I'm struggling with what you're trying to 8 <sup>8</sup> different connections in different points in what ask me. Because it seems like to me --9 <sup>9</sup> I was reviewing. I can't recall whether I read it seems to me as if the litigators on <sup>10</sup> this particular transcript in any -- any detail. 10 both sides of a case like this understand 11 Are you aware that there have been a whole lot more about how the material 12 12 more than 10 trials involving claims of use of and references get generated in 13 Johnson's Baby Powder and ovarian cancer? 13 litigation than I do. 14 I'm aware there have been several 14 BY MR. HEGARTY: 15 <sup>15</sup> trials and there are trials -- and there are Let me ask it in a different way. <sup>16</sup> trials ongoing. I don't mentally separate the 16 Do you know how they went about <sup>17</sup> state trials from the MDL trials. Again, I choosing which Bates-numbered documents to send to <sup>18</sup> approach this as a regulatory expert. I don't you, other than those you may have asked for? approach this as a litigator. 19 DR. THOMPSON: Object to form. 20 Did you ask to see the trial 20 THE WITNESS: No, I don't. <sup>21</sup> transcripts in all the cases that have been tried? 21 BY MR. HEGARTY: 22 No. 22 And do you recall asking plaintiffs' 23 counsel for any specific internal company Q. Did you read all of the <sup>24</sup> Bates-numbered documents that begin on page 12 and <sup>24</sup> documents? Page 107 Page 109 <sup>1</sup> carry over to page 17 -- I'm sorry -- page 18? I was -- by -- by document 2 <sup>2</sup> identification, no, because I wouldn't know what No, certainly not. 3 O. Did you select -- did you select or <sup>3</sup> the documents were. I was very interested in <sup>4</sup> ask for any of the Bates-numbered documents that <sup>4</sup> documents that would relate to your client's are referenced on these pages? <sup>5</sup> understanding of its regulatory obligations. I 6 <sup>6</sup> was very interested in documents that would relate DR. THOMPSON: Object to form. 7 <sup>7</sup> to your client's approach to its informational THE WITNESS: I don't know --8 I don't know the answer to that. environment for consumers, which gets into the 9 marketing and advertising space. I approach -- I approach this 10 10 the way I would approach any regulatory I was very interested in your 11 investigation, any analytic project. client's documents that reflected your client's 12 It's a slightly different set of citation <sup>12</sup> best understanding of the relevant science. 13 13 Beyond that, you know, the references are provided practices than what one might have in law 14 review, which, as I've said, is also very for this document, I am certainly hoping and 15 assuming, in compliance with law and beyond, but different from one would have in the 16 that doesn't really go to the heart of my medical or health policy literature, 17 17 which is different from what one might opinions. 18 18 have in a national academy's report; and, Q. As far as the subject areas that you 19 just referenced in your answer to my last you know, I relied on plaintiffs' counsel 20 to understand what the requirements and question, did you ask plaintiffs' counsel for all 21 norms of this type of a report were. <sup>21</sup> the documents that Johnson & Johnson had produced <sup>22</sup> BY MR. HEGARTY: on those subject areas? 23 23 Did plaintiffs' counsel select at DR. THOMPSON: Object to form. <sup>24</sup> least some of the Bates-numbered documents that 24 THE WITNESS: No. I would

Page 110 Page 112 1 <sup>1</sup> materials that were provided to you, correct? assume that the all -- that asking for 2 all of anything in this type of I made very specific requests of 3 plaintiffs' counsel, and I made very clear that I litigation would take me years to review. 4 I asked for things that seemed relevant <sup>4</sup> wanted material on both sides of every question 5 and important and that were balanced and and evaluated that. 6 reflected arguments on both sides. What did you do to confirm that you <sup>7</sup> BY MR. HEGARTY: got material on both sides of the -- of a Well, if you didn't ask for all of question? the documents relating to the subject areas you DR. THOMPSON: Object to form. 10 THE WITNESS: Well, for described, how do you know if you got all the relevant documents on those subject areas? 11 example, you know, I spent a good amount 12 12 DR. THOMPSON: Object to form. of time going through Johnson & Johnson's 13 13 THE WITNESS: How? (Laugh). submission to Health Canada, which 14 14 It's -- it's interesting to be asked clearly included all of the relevant 15 15 these questions because, you know, one is science and the counterarguments to 16 16 reconstructing how one does research in science establishing a causal connection 17 17 between perineal talc exposure and pretty much anything. 18 18 You know, what I -- what I did ovarian cancer. 19 19 is, it's a -- it's an iterative process I mean, I felt like that was a 20 20 as it would be for you evaluating a case. pretty good reflection of what the 21 21 You look at the different pieces of -- of defense would offer on the scientific 22 22 the case. You look at different side. 23 23 arguments and different counterarguments On the regulatory side on the 24 24 and the underlying facts. And if you marketing side, there seemed to be less Page 113 Page 111 1 feel like you have a sense of each of material of it, and I did my best to 2 what you consider the material issues, 2 assemble what there was and I asked 3 3 repeatedly to see if there was anything you stop. 4 4 You know, if you feel like you more. 5 5 have a one-sided view of five of the BY MR. HEGARTY: 6 issues, then you investigate until you 6 You mentioned a submission to Health Q. 7 get the other side of those five issues. Canada. You said you have it in front of you. 8 8 And if you think you have a piece of What's the date of that submission? 9 9 information you just -- that's just A. I have to go back to see. 10 10 missing, you pursue that. (Reviews document.) 11 I mean, you don't -- I've 11 Well, let me ask it different. 12 12 never ever started any project as a Is there a beginning Bates number on 13 it? 13 lawyer, as a physician, as a researcher 14 as a professor where I say, give me 14 Well, so -- so this -- so this 15 everything. That's -- that's discovery, comprehensive review document that comes from 16 not the way I do an expert report. Johnson & Johnson Consumer, Inc. said its current 17 BY MR. HEGARTY: as of March 17, 2020, and the Bates number is 18 <sup>18</sup> P-1851. O. Well, that said, I mean, I have to 19 <sup>19</sup> disagree that I -- that you approach it the way I Q. Through what? <sup>20</sup> would approach it, which you said in your answer. 20 Oh, I'm sorry. That's the exhibit A. <sup>21</sup> Because I would not approach it the way that you <sup>21</sup> number. approached it. 22 What's the beginning number? Q.

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A.

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I'm sorry.

<sup>24</sup> plaintiffs' counsel as far as some of the

You do agree that you relied on the

What's the beginning Bates number?

Page 114 Page 116 1 Certainly. A. Sorry. You're speaking litigator A. Did you read the entirety of all the <sup>2</sup> language. O. 3 medical and scientific studies referenced in Q. Okay. 4 Page 1 of 4,528. It's a long Exhibit No. 5? <sup>5</sup> document containing a lot of assessments and No, but I read probably between 10 <sup>6</sup> scientific references. I'm happy to hand -- hand and 20 scientific studies in their entirety. <sup>7</sup> it to you if you can. With regard to the scientific Yeah, I'll take a look at it. studies that are listed in Exhibit No. 5, were all O. 9 of those provided to you by counsel for the There is -plaintiffs? 10 A. Oh, some -- yeah, I still don't know 11 11 what vou're --DR. THOMPSON: Object to form. 12 12 DR. THOMPSON: May I point? THE WITNESS: In other words, 13 13 MR. HEGARTY: Sure. did anyone else provide them or did I 14 14 find them on my own? DR. THOMPSON: He's asking for 15 the beginning Bates number. 15 BY MR. HEGARTY: 16 THE WITNESS: Okay. That's 16 Q. Correct. 17 17 now -- now it's an eye test. All right. They were all provided by counsel 18 So it ends 485273 and it goes through for the plaintiffs. 19 19 So the follow-up question is: Did 485527. 20 you find from your own independent review any BY MR. HEGARTY: 21 medical literature, scientific or medical What does it say on the top of the 22 very first page? literature? 23 23 Top? A. DR. THOMPSON: Object to form. 24 24 THE WITNESS: Interesting Q. What is the title? Page 117 "Attachment B Johnson's Baby Talcum question. 2 <sup>2</sup> Powder: A Comprehensive Review 17 March 2020." I'm not sure I recall. I 3 3 Q. Okay. Thank you. think it's -- it's fair to say that the 4 There are Bates numbers in -- well, vast majority of scientific sources were 5 <sup>5</sup> go back to Exhibit B, Doctor. This is this provided by counsel for the plaintiff, or <sup>6</sup> (indicates). 6 were referenced or described in material 7 7 A. Yes. that was made available, such as Johnson 8 8 List of materials. & Johnson's Health Canada submission. 9 9 Do you still have that exhibit in It is possible I surfaced one 10 10 front of you? or two things on my own as I looked 11 11 A. around. 12 O. If you look at page 18, the very 12 BY MR. HEGARTY: last page of that set of materials, there's some 13 Did you do any type of PubMed or Bates number documents at the end listed WCD. other search vehicle that doctors use to -- to 15 Do you know who produced those search across the medical and scientific <sup>16</sup> documents? literature as part of your work on this case? 17 17 A. I did not do a PubMed search. 18 18 You said the materials that Q. Do you know if you read those O. 19 documents? plaintiffs' counsel provided to you were all sent 2.0 Not without looking at documents. via Dropbox? A. 21 21 There are a number of medical and They were all made available in <sup>22</sup> scientific studies that are included in this list <sup>22</sup> Dropbox and some of them were probably sent as of material. <sup>23</sup> e-mail attachments, but those would duplicate what 24 <sup>24</sup> was in the Dropbox. Do you see that?

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- Q. On page 2 of your report.
- <sup>2</sup> A. Report or the references?
- <sup>3</sup> Q. The report. Now we're back to the <sup>4</sup> report, which is Exhibit No. 4.
- In the Methodology section, page or
   paragraph 9, you say that you were asked to answer
   the following questions, and you list two
- <sup>8</sup> questions there in that paragraph, right?
- <sup>9</sup> A. Yes.

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- Q. Who asked you to answer those questions?
- A. The -- I worked with the plaintiffs' counsel to formulate the questions that I would answer in my opinion.
- Q. You state as well in that paragraph that you were not asked to provide an opinion on whether talc causes -- talcum powder products cause cancer, correct?
- <sup>19</sup> A. Correct.

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- Q. In this case, you are not offering opinions on causation, correct?
- A. I am not offering my independent
   professional assessment of causation. I am making
   supportable inferences about causation and risk

- <sup>1</sup> something that was referenced in -- in some,
- <sup>2</sup> though not all, of the reports. It is the -- it
- <sup>3</sup> is the type of, you know, causation algorithm that
- <sup>4</sup> would be familiar in a lot of settings.
- In my work, I tend not to be. My expertise is, again, an expertise that involves a lot of connections and a lot of considerations and
- 8 a lot of history. Nothing I do requires following
   9 an algorithm.
- Q. You did not do a Bradford Hill
   analysis with regard to talcum powder use and
   ovarian cancer, right?
- A. I did not. I did read references in some of the material to Bradford Hill criteria and -- and ovarian cancer and talc.
- Q. You did not do a formal risk
   assessment with regard to talcum powder use and
   ovarian cancer, correct?
- <sup>19</sup> A. I certainly didn't do a formal risk <sup>20</sup> assessment. I read a lot of risk assessment <sup>21</sup> material here.
- Q. You did not do any type of Bradford Hill analysis or formal risk assessment with regard to asbestos and ovarian cancer, correct?

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and uncertainty based on other expertise from
 other individuals.

Q. And you have not done your own
 assessment of the medical and scientific
 literature as to whether talcum powder products
 can cause ovarian cancer, correct?
 DR. THOMPSON: Object to form.

THE WITNESS: I have. I have done what I would consider to be a first pass review of the scientific literature that would be appropriate for, say, writing a solid article in the peer literature -- peer-reviewed literature about the regulatory requirements at issue here.

I would be perfectly comfortable taking, you know, salient points from my report and basing a peer-reviewed article on that.

## <sup>20</sup> BY MR. HEGARTY:

- Q. Do you know what a Bradford Hill analysis is?
- A. I do know. It wasn't something -- I can't recite each of the criteria. It was

DR. THOMPSON: Object to form.

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THE WITNESS: With respect to asbestos and cancer, the -- the causation analysis is from a policy perspective already definitive. There's no reason to do that.

# <sup>7</sup> BY MR. HEGARTY:

- Q. You did not do it?
- A. Did not. No need.
- Q. You also did not do a Bradford Hill or risk assessment analysis with regard to heavy metals and ovarian cancer, correct?
  - A. That's correct.
- Q. You didn't do a Bradford Hill or risk assessment analysis with regard to fragrances and cancer risk, correct?
- A. I don't believe there's actually enough information in existence regarding the fragrances in these particular products for anyone to do that analysis.
- Q. You did not do any type of Bradford Hill or risk assessment analysis with regard to fibrous talc and ovarian cancer, correct?
- A. Again, fibrous talc is treated on a

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par with asbestos in enough of the material that I
 read that I would give the same answer as for
 asbestos.

Q. Okay. Did you assume for purposes of your report that talcum powder use causes ovarian cancer?

DR. THOMPSON: Object to form. THE WITNESS: Did I assume that talcum powder use causes ovarian cancer? Certainly not. It's talcum powder use, you know, that's a very general phrase. I could use talcum powder, you know, in many ways. Women could use talcum powder in many ways and, you know, I would have no basis for that assumption.

That's different from talking about what's at issue in this case, which are specific applications and specific ways over specific periods of time with specific products whose contents are not well-established.

# <sup>23</sup> BY MR. HEGARTY:

Q. Well, did you assume for purposes of

The information that I take

out of all of this material, you know, actually involves context that may not be similar to the context in, say, a particular causation report.

#### BY MR. HEGARTY:

Q. You agree that you have not reviewed
 all of the defense expert reports as it relates to
 talcum powder use and ovarian cancer?

A. Correct.

Q. You agree that before someone
testifies in court that talcum powder causes
ovarian cancer, they should have done a
comprehensive analysis of all the medical and
scientific literature on the issue, correct?

DR. THOMPSON: Object to form.
THE WITNESS: I don't know

THE WITNESS: I don't know the answer to that because I have not been asked to testify in court as to whether talcum powder causes ovarian cancer.

# <sup>22</sup> BY MR. HEGARTY:

Q. You certainly didn't do acomprehensive analysis of all the medical and

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your report that any manner of talcum powder usecan cause ovarian cancer?

DR. THOMPSON: Object to form.
THE WITNESS: I did not make
the assumption. I relied on the
scientific conclusions of scientific
experts' published literature. I
evaluated the confidence intervals, the
risks associated, the scientific design
for the science, but also the assessments
of other umbrella bodies that have done
some type of systematic review for
whatever their own purposes are.

Understand that my expertise fundamentally situates each one of these documents in a context, and it's the context that collectively forms the basis for my opinion.

You know, what year, for what purpose, by what organization, subject to what types of business constraints, what types of political considerations, what types of resource constraints, that's what I do.

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scientific literature on talcum powder use and
 ovarian cancer, correct?

DR. THOMPSON: Object to form. THE WITNESS: I feel that I did a sufficient review of the scientific literature on which to base my opinions, and I actually -- actually feel quite strongly about this. Because it's one of the things that, given the preparation of this report, I made sure I could do, and I feel I have the scientific and medical background to understand that.

So I actually made a very specific effort to consider the underlying science here.

## <sup>16</sup> BY MR. HEGARTY:

<sup>17</sup> Q. You agree you have not analyzed all <sup>18</sup> the animal studies on talcum powder use and <sup>19</sup> ovarian cancer, correct?

DR. THOMPSON: Object to form. THE WITNESS: I agree.

### <sup>22</sup> BY MR. HEGARTY:

Q. You have not looked at all the cellstudies on talcum powder use and ovarian cancer,

Page 126 Page 128 <sup>1</sup> correct? <sup>1</sup> ovarian cancer, correct? 2 DR. THOMPSON: Object to form. 2 DR. THOMPSON: Object to form. 3 THE WITNESS: Again, if 3 THE WITNESS: That I read all 4 4 the cell studies. Again, I really find you're building the number of things I 5 haven't looked at, I don't really know 5 it's hard to answer questions where I 6 6 what the denominator is here. don't know the denominator, but I'm happy 7 7 to agree with you that there are many If, for example, there were 8 8 two animal studies that were major animal things that have been studied that might 9 9 studies and that's all the animal studies be plausibly related to these questions 10 10 there were, chances are I asked for them, that have been published in scientific 11 11 I received them, and I looked at them. literature that I have not. But that 12 12 So if you're giving me would be true of literally any question 13 13 denominators, you know, where that's you could ask me on any topic. 14 14 greater than 10 such studies, I will be BY MR. HEGARTY: 15 happy to agree that I didn't review all 15 Well, let me ask it a different way. O. 16 16 of them; but if the denominator on some You didn't go out and try to find 17 of this is there were three studies, all the cell studies on talcum powder use and 18 possibly I did. ovarian study, correct? BY MR. HEGARTY: 19 Correct. I do have to reinforce 20 Let me ask it a different way. that I understand the difference between the 21 If you reviewed the submission that questions you're asking and the information I'm <sup>22</sup> Johnson & Johnson made to Health Canada that we trying to provide. <sup>23</sup> talked about earlier that are in your notebook, I made a very serious effort to <sup>24</sup> you know that there are hundreds of animal cell <sup>24</sup> consider the best available science on both sides Page 127 Page 129 <sup>1</sup> and to consider it over time. <sup>1</sup> and epidemiologic studies cited in that document, correct? You didn't try to go out and make 3 DR. THOMPSON: Object to form. <sup>3</sup> sure you had found and read all the epidemiologic 4 THE WITNESS: I would want <sup>4</sup> studies on talcum powder use and ovarian cancer, 5 <sup>5</sup> correct? to -- as I would for anything, I would 6 A. The epidemiological studies, we -want to review the document. There were 7 <sup>7</sup> we can certainly go into particular studies; but, many studies cited. How relevant they 8 again, I find it very hard to answer these -are to the questions Health Canada was 9 <sup>9</sup> these denominator questions. There tend to be a considering is a matter of debate. <sup>10</sup> BY MR. HEGARTY: small number of case-controlled studies, a small 11 Did you read the entirety of that number of cohort studies. O. 12 12 There's a whole bunch of document? I read everything in that -- in the differences, as you well know, between studies <sup>14</sup> pages that, you know, I have here. I read that are looking at sort of pathways to ovarian <sup>15</sup> everything that was text that I could decipher. cancer development. Each of the things in terms <sup>16</sup> There's a lot of things that are in tabular or of inflammation, in terms of migration, in terms supplemental fashion; and, no, I did not read of deep embeddedness of talc in ovaries. 18 <sup>18</sup> those things. There's all sorts of things that 19 anyone with, you know, a basic expertise in You agree, though, that you did not read all of the studies that are cited in that medicine or science will be able to step you 21 document? <sup>21</sup> through; and each one of these is going to be 22 <sup>22</sup> established scientifically over time, often for A. I'm sure that's the case. 23 And you can't say sitting here today <sup>23</sup> reasons that are not reasons that are about

<sup>24</sup> that you read all the cell studies on talc and

<sup>24</sup> Johnson & Johnson baby powder and ovarian cancer,

<sup>1</sup> and all of these, you know, collectively inform <sup>1</sup> an article where you've cited to internal company <sup>2</sup> scientific judgments. <sup>2</sup> documents? So I'm happy to make any study you A. I don't. I would have to go back <sup>4</sup> want to offer me. Please show me a study that you <sup>4</sup> and review articles, but there wouldn't have been <sup>5</sup> think would be relevant to my conclusions; but at <sup>5</sup> internal company documents that were made directly <sup>6</sup> the end of the day, remember I'm not offering a <sup>6</sup> available to me on a confidential basis. They <sup>7</sup> scientific opinion on causation of ovarian cancer <sup>7</sup> would have been internal company documents <sup>8</sup> from your product. <sup>8</sup> involving, say, tobacco or -- you know, there's a <sup>9</sup> lot of areas. Silicon breast implants. My question was different and listen 10 <sup>10</sup> to my question. There are various things I've You did not, as part of your <sup>11</sup> written about over the years that involve <sup>12</sup> methodology in this case, go out and search across <sup>12</sup> hazardous products that involve liability where <sup>13</sup> all the medical and scientific literature to make 13 internal corporate documents may well be part of <sup>14</sup> sure you had found all of the epidemiologic 14 the analysis, but I would have to go back and <sup>15</sup> studies looking at talcum powder use and ovarian 15 look. 16 16 cancer? Besides sitting here today, can you 17 A. As I said before, I did not do a cite for me any published articles of yours where you cited in that article internal company <sup>18</sup> PubMed search. 19 Cite for me any instances where you documents? 20 <sup>20</sup> have analyzed before this -- getting involved in A. Not that I --21 <sup>21</sup> this case a cosmetic product, its manufacturer, DR. THOMPSON: Object to form. 22 <sup>22</sup> and the applicable regulations like you've done in THE WITNESS: Not that I can 23 <sup>23</sup> your report? recall right now, but I've written a lot 24 24 DR. THOMPSON: Object to form. of articles. Page 131 Page 133 1 THE WITNESS: I have not had <sup>1</sup> BY MR. HEGARTY: 2 cause to analyze a cosmetic manufacturer. Have you ever written an article 3 I would emphasize that I, as a good <sup>3</sup> where you've cited to an expert report in 4 litigator mind in a litigation context, I <sup>4</sup> litigation? 5 analyze regulatory problems across DR. THOMPSON: Object to form. 6 industries all the time. 6 THE WITNESS: I also don't <sup>7</sup> BY MR. HEGARTY: know that for a fact, but I can't recall Have you ever published an analysis, any. <sup>9</sup> like you've done here, looking at the manufacturer BY MR. HEGARTY: 10 of a cosmetic product and the product itself? In paragraph 10 of your report, you 11 DR. THOMPSON: Object to form. discuss the literature that you reviewed. 12 12 THE WITNESS: No. Did anyone help you in reviewing the 13 BY MR. HEGARTY: 13 literature or searching for literature, someone at vour office or otherwise? 14 Have you ever published an article <sup>15</sup> where you've given opinions based on internal 15 A. No, I didn't -- didn't use any company documents? <sup>16</sup> research assistants or any -- any other 17 individuals for assistance here. DR. THOMPSON: Object to form. 18 18 THE WITNESS: I'm sorry. If O. Other than doing you mentioned a 19 <sup>19</sup> Google search before, did you do -- use any other by "opinion" do you mean an expert 20 witness opinion in litigation? We've formal methods of searching for materials in 21 preparing your report? established that I don't do that very 22 22 DR. THOMPSON: Object to form. much.

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Well, when have you ever published

<sup>23</sup> BY MR. HEGARTY:

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THE WITNESS: So I reviewed

sort of the leading casebook on food,

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drug, and cosmetic regulation that had a chapter on -- on cosmetic regulation that

gave rise to a whole bunch of sources that I may have, you know, Googled to

5 look at a Federal Register something 6 or -- or some particular reference, some 7 other -- some earlier cosmetic-related

8 controversy.

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You know, this is -- this is a casebook, you know, including among its authors Peter Hutt, who, you know, is a long-time expert I have great respect for who tends to represent the cosmetics industry in a lot -- in a lot of policy-related proceedings.

So yes, I did a lot of additional research based on things that I -- I discovered reviewing that material, reviewing other material. It's, again, standard practice with me to follow what you think are important leads.

<sup>23</sup> BY MR. HEGARTY:

Q. With regard to the materials that <sup>1</sup> considered for purposes of preparing your report?

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DR. THOMPSON: Object to form. THE WITNESS: My description of the methodology at a relatively high level is contained in paragraphs 9 and 10 and reflects exactly how I would go about a regulatory analysis in any health-related area, in the safety risk-related area and, frankly, a whole lot of regulatory areas that are -- that are not about human health and safety where there are governing statutes. There are regulatory systems. There are self-regulatory systems. There are balances of federal and state authority.

There is a historical context, a political context, an industrial, and organizational context. Sometimes a professional context, which is, of course, very important to distinguishing drug regulation from cosmetic regulation.

This is all routine for me. It's exactly what I do if I'm writing an article to teach a class or even just,

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<sup>1</sup> you did review, did you assign any weight --

<sup>2</sup> formally assign any weight to the materials for

purposes of writing your report?

DR. THOMPSON: Object to form.

THE WITNESS: I mean, there are basic hierarchies, you know, in terms of legal authority. There are, you know, but other than that, there are no

9 specific criteria for assigning weight.

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I mean, one's regulatory expertise is not 11 the same as doing a quantitative risk

12 analysis or a meta-analysis.

# 13 BY MR. HEGARTY:

14 Well, in preparing your report, did you assign a numerical value to the weight of the 16 materials that you reviewed?

> A. No.

DR. THOMPSON: Object to form. THE WITNESS: Except perhaps how heavy they were. (Laugh).

<sup>21</sup> BY MR. HEGARTY:

22 Do you explain anywhere in your report the methodology that you went about that

<sup>24</sup> you used in identifying the materials that you

you know, at home thinking about a

current event.

#### <sup>3</sup> BY MR. HEGARTY:

Did plaintiffs' counsel give you <sup>5</sup> access to a database of all the documents that <sup>6</sup> Johnson & Johnson had produced in this case?

They didn't give me direct access to a very large universe of documents. Presumably,

<sup>9</sup> they gave me access to the documents they thought

were relevant, but I actually don't know how they

assembled their documents and do their management. 12 You did not yourself do any type of

13 search over a database of documents produced using search terms to look for company -- internal company documents --

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I did not.

17 O. -- that Johnson & Johnson produced?

A. I did not.

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19 But plaintiffs' counsel did provide

20 you with some internal company documents that have

<sup>21</sup> been produced in this case, correct?

A. Correct.

23 Q. These were not documents you

<sup>24</sup> selected from a larger set, correct?

Page 138 1 <sup>1</sup> some of these documents that the P numbers are A. Except --2 <sup>2</sup> plaintiffs' exhibits from trial? Did you DR. THOMPSON: Object to form. 3 THE WITNESS: Except insofar understand that? 4 as I asked for the things that I thought A. I do understand that. 5 were not evident from what I had already Did you ask plaintiffs' counsel to O. 6 reviewed. For example, asking for give you all the defense exhibits that had been 7 material that would bear on marketing introduced at trials? 8 decisions, marketing languages, Α. I asked. I did not ask for all the 9 strategies over time for Johnson & defense exhibits. I did not ask for all the 10 Johnson consumer products and plaintiffs' exhibits. I did ask for the defense 11 specifically for Johnson's Baby Powder. perspective on the issues that were relevant to my 12 BY MR. HEGARTY: 12 opinions. 13 13 Did you ever ask for specific Q. Did you -document by Bates number or title of that 14 I asked --A. 15 <sup>15</sup> document? Q. I'm sorry. 16 Not to my recollection. It would 16 I'm sorry. I asked repeatedly for A. 17 never have been by Bates number. It's possible that. <sup>18</sup> that there was in a deposition transcript some 18 Well, did you ask specifically for 0. <sup>19</sup> reference to a document that I then requested. I defense exhibits that had been introduced at <sup>20</sup> don't recall. trial? 21 21 Q. Are you aware that Johnson & Johnson A. No. 22 And what did you do to confirm that <sup>22</sup> has produced thousands of documents regarding O. <sup>23</sup> communications with FDA, thousands of documents, the plaintiffs' counsel gave you a fair <sup>24</sup> if not hundreds of thousands of documents. <sup>24</sup> representation of the documents on the issues you Page 139 Page 141 <sup>1</sup> regarding testing of talc for asbestos. <sup>1</sup> talk about in your report? DR. THOMPSON: Object to form. Are you aware of that? 3 3 I am aware of a number of FDA THE WITNESS: I -- my 4 <sup>4</sup> contacts and a number of testing-related materials confirmation was looking at the internal 5 <sup>5</sup> that Johnson & Johnson has introduced into this consistency of what I was reviewing and <sup>6</sup> litigation. I have no idea what number they are, 6 the opinions I was formulating based on 7 <sup>7</sup> and, again, I have no idea of how relevant they it. I think I would have noticed <sup>8</sup> are. 8 significant biases. I think I would have 9 In the document we're looking at noticed significant gaps. 10 <sup>10</sup> before, Exhibit No. 5, there are a number of But, no, I didn't do any <sup>11</sup> plaintiff exhibits that are identified by P 11 structured confirmation and I certainly 12 numbers beginning on page 16 and carrying over to 12 didn't -- I mean, other than an informal 13 13 page 17. request, I'm not sure what I could have 14 14 Do you see those pages? done. So I didn't. 15 A. Yes. BY MR. HEGARTY: 16 Do you recall looking at any of the 16 Have you ever outside of any documents that have a P number on them, an exhibit 17 litigation work in your professional career ever 18 sticker? relied on documents that were selected for you to 19 review by a plaintiff's lawyer? I certainly have looked at documents <sup>20</sup> with P numbers, such as Johnson & Johnson response 20 DR. THOMPSON: Object to form. 21 21 to Health Canada, which we just discussed, which THE WITNESS: Again, yes, in 22 <sup>22</sup> had a P number on it. I noticed there were P the sense that I was the principal 23 numbers on some documents. investigator of a very large 24 Did you understand in looking at 24 investigation on medical malpractice

policy that was funded by the Pugh Trust,

- 2 which involved outreach to a whole lot of
- 3 people and, you know, that included
- 4 plaintiff's lawyers, defense lawyers,
- 5 insurance companies, you know, physician,
- 6 and hospital organizations and others.
- 7 And, you know, when I asked for materials
- 8 from each of them, I got the materials
- 9 that they gave me.

#### <sup>10</sup> BY MR. HEGARTY:

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- 11 My question was as to any
- non-litigation work you've ever done, not regular litigation.
- 14 A. This is non-litigation.
- 15 Q. Which part?
- 16 Everything I just said was A.
- 17 non-litigation.
- 18 And what was the situation? O.
- 19 A large grant program that I led on
- 20 medical liability.
- 21 Let me ask it a different way.
- 22 In any publication of yours, have
- <sup>23</sup> you ever relied in the materials that you reviewed
- <sup>24</sup> on a plaintiff's lawyer to provide you the
- Page 143
- <sup>1</sup> materials?
- To provide me some of the materials?
- <sup>3</sup> I'm sure I have.
- When have you ever written an <sup>5</sup> article that where you relied on materials that
- <sup>6</sup> came -- that came from a plaintiff's lawyer?
- If I were writing on medical
- <sup>8</sup> liability and making certain points and sometimes
- <sup>9</sup> the only way you could get information about
- <sup>10</sup> opinions that were not publicly reported or other
- <sup>11</sup> insights, I'm relying on the people I'm talking
- <sup>12</sup> to.
- 13 Again, perhaps I'm misunderstanding your question.
- 15 Q. Yeah.
- Have you ever in any article that you've published ever relied on the materials for
- <sup>18</sup> that article from a plaintiff's lawyer to produce
- 19 materials produced in litigation?
- I think we're also back to sort of
- <sup>21</sup> some ambiguity between: Are you drawing a
- <sup>22</sup> distinction between considered or relied on or can
- <sup>23</sup> we use relied in a casual sense of --24
  - Let me ask it a different way.

- In any publication of yours, have
- <sup>2</sup> you ever reviewed in preparing that publication
- <sup>3</sup> materials that were provided to you from a
- <sup>4</sup> plaintiff's lawyer that were produced in a
- <sup>5</sup> litigation?
- A. That were -- that were -- I'm sorry.
- <sup>7</sup> That were produced through discovery in the
- litigation?
- Q. Correct.
- 10 A. I'm sorry. I misunderstood the
- question.

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- Not to my knowledge.
- 13 Are you aware that Johnson & Johnson O.
- 14 has put on a website all the facts about talc,
- 15 thousands of documents that have been introduced
- in the lawsuits in -- in these cases?
  - I reviewed -- on my own initiative,
- <sup>18</sup> I reviewed some of The Facts About Talc web pages
- that Johnson & Johnson makes available
- consumer-facing. I didn't -- I didn't think of
- <sup>21</sup> that as a litigation-related resource, and if
- 22 there were links to a document trove, I didn't --
- <sup>23</sup> I didn't notice that.
  - So you did not review the internal Q.

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- <sup>1</sup> Johnson & Johnson documents that are on that Facts
- About Talc website?
  - DR. THOMPSON: Object to form.
  - THE WITNESS: Again, it
- 5 depends. It depends what they were, and
- 6 if you would like to show me something,
- 7
- perhaps I'll remember that I saw it or 8
- 9 Again, that Facts About Talc 10 website that I saw contained, you know,
- 11 various statements and various links to
- 12
- other pages. Some of which may have been 13 to documents rather than HTML sites, and
  - so it's possible.
  - But, you know, did I look comprehensively through something that was presented as a database of documents?
- 18 No, I did not.
  - MR. HEGARTY: Why don't we go ahead and take a break. It's been
- 21 another hour and some.
  - DR. THOMPSON: Okay.

MR. HEGARTY: Okay. Go off

record.

Page 146 Page 148 1 (Recess: 10:40 a.m. -<sup>1</sup> ovarian cancer specific. 2 11:02 a.m.) Had you read any articles prior to 3 MR. HEGARTY: We are back on <sup>3</sup> being contacted by plaintiffs' counsel looking at 4 <sup>4</sup> heavy metal use and ovarian cancer -- heavy metal the record. <sup>5</sup> BY MR. HEGARTY: exposure and ovarian cancer? A. Doctor, we were talking about No. <sup>7</sup> Exhibit No. 5 and in particular some of the O. All of the opinions that are set out <sup>8</sup> literature that's listed on there. in your report that we marked previously as <sup>9</sup> Exhibit No. 4 were formed after you were contacted Had you read any medical or <sup>10</sup> by plaintiffs' counsel about testifying as an <sup>10</sup> scientific literature regarding talc and ovarian <sup>11</sup> cancer before being contacted by counsel for expert in this case, correct? DR. THOMPSON: Object to form. plaintiffs in this case? 12 13 13 I probably had, but I don't recall THE WITNESS: Yes. After I <sup>14</sup> the specifics. It's been an issue for a long 14 was contacted to consider whether I would 15 time. 15 be an expert in this case, yes. 16 When you say you probably had, would <sup>16</sup> BY MR. HEGARTY: 17 that have been, if at all, back when you were in You mentioned that prior to being medical school and then doing your internship or contacted by counsel for plaintiffs in this case residency? that you had been aware of an alleged link between 20 No. It would more likely have been talcum powder use and ovarian cancer, correct? <sup>21</sup> during my teaching career because health and 21 A. Correct. 22 <sup>22</sup> safety regulation and health law policy are what I O. And you talked generally about news <sup>23</sup> do. sources and other general perhaps sources that you 24 But sitting here today, can you say <sup>24</sup> would see in your work that refer to -- referred Q. Page 149 Page 147 <sup>1</sup> definitively that you had read any medical <sup>1</sup> to talcum powder use and ovarian cancer. <sup>2</sup> literature, whether it's an epidemiologic article Are you able to cite any specific <sup>3</sup> or cell study or animal study, on talcum powder <sup>3</sup> things you had read prior to being contacted by <sup>4</sup> use and ovarian cancer before being contacted by <sup>4</sup> Dr. Thompson as it relates to talcum powder use <sup>5</sup> counsel for the plaintiffs in this case? <sup>5</sup> and ovarian cancer? I believe that it's extremely likely A. I can't cite them specifically. A. <sup>7</sup> that I did because it's a big issue. <sup>7</sup> Most of the things I would see in the ordinary Can you identify for me any article course would be things that had either a you had read or the time period in which you had <sup>9</sup> law-related or a health policy-related connection. read such an article? 10 10 Most of my, you know, daily news feed type sources 11 are not, you know, the clinical literature as Not specifically. 12 O. So are you able to identify for me 12 much. <sup>13</sup> any article that you had read -- medical or Now if something had shown up that 14 scientific article about talcum powder use and was, you know, JAMA New England Journal style <sup>15</sup> ovarian cancer before being contacted by publication or, you know, abstracted in some 16 plaintiffs' counsel? compendium, you know, major clinical News of the 17 Week, the old AMA news sites, then I would have A. Can I identify it now? No. 18 O. Had you read any article looking at seen it in that connection. <sup>19</sup> asbestos and ovarian cancer prior to being 19 But, you know, this is a major contacted by plaintiffs' counsel in this case? concern and a major source of -- of potential 21 <sup>21</sup> liability and litigation. So, of course, as a law I have read a lot of <sup>22</sup> asbestos-related documents over the years in dribs <sup>22</sup> and medical school professor, I've seen <sup>23</sup> and drabs as things came up. Most of them were <sup>23</sup> references. <sup>24</sup> mesothelioma related. I don't recall any being on Q. As a medical student and then when

Page 152 <sup>1</sup> you finished law and medical school and did some A. Yes. <sup>2</sup> clinical practice in medicine, did you ever read 2 O. As this letter shows, and as you <sup>3</sup> anything or were you ever taught anything as it <sup>3</sup> know from your own analysis, FDA did receive two <sup>4</sup> Citizen Petitions asking that a warning be placed <sup>4</sup> relates to talcum powder use and ovarian cancer? Not that I recall. <sup>5</sup> on talc products, and they give a couple examples 6 <sup>6</sup> of those types of warnings on the first page of You -- first back up. 7 Have you ever taught in any course <sup>7</sup> this exhibit, right? <sup>8</sup> of yours -- let me ask it a different way. They don't give examples. They give Have you ever referenced in any the specific warnings that were requested in the 10 course you have taught anything about talcum Citizen's Petitions. 11 powder use and ovarian cancer or litigation 11 Ο. Fair enough. 12 involving talcum powder use and ovarian cancer? 12 And in 2014, FDA determined that the 13 Not that I recall. <sup>13</sup> data did not demonstrate a causal association 14 <sup>14</sup> between talcum powder use in the perineal area and Q. You cite in your report to such organizations as IARC, Health Canada, and the FDA. ovarian cancer, correct? 16 Do you recall that? 16 To quote from that letter, as I 17 A. Yes. described in paragraph 150 of my opinion, the 18 So do you agree that it was Q. letter says: important for your methodology in this case to 19 "While the growing body of evidence consider what these health authorities have to say to support a possible association ... is difficult <sup>21</sup> to dismiss, the evidence is insufficient for FDA about talc use and ovarian cancer, correct? 22 DR. THOMPSON: Object to form. to require as definitive a warning as you are 23 seeking." THE WITNESS: Correct, with 24 24 the addition that my opinion is It's not exactly what you had quoted Page 153 Page 151 fundamentally about regulatory compliance <sup>1</sup> there. 2 and self-regulatory conduct and not about Well, on the first page of the -- of O. 3 causation. <sup>3</sup> Exhibit No. 7, second last paragraph, last line, <sup>4</sup> it says: <sup>4</sup> BY MR. HEGARTY: On page 11 -- let me not -- I don't "FDA did not find that the data <sup>6</sup> need to reference your report. Let me just back <sup>6</sup> submitted presented conclusive evidence of a <sup>7</sup> up. <sup>7</sup> causal association between talc use and the You mentioned earlier when you went perineal area and ovarian cancer." 9 <sup>9</sup> through the materials that you had in front of you Correct? <sup>10</sup> that you -- the April 2014 FDA letter denying two Certainly with the emphasis on <sup>11</sup> Citizen's Petitions seeking warnings about the <sup>11</sup> "conclusive" which is the only word that makes 12 risk of ovarian cancer with talcum powder use, <sup>12</sup> that consistent with the language that I quoted to 13 correct? 13 you. 14 14 And FDA did a comprehensive review Α. Correct. O. 15 of the science in rejecting these opinions, MR. HEGARTY: I'm going to 16 correct? I'm sorry. These petitions, correct? mark as Exhibit No. 7 a copy of that 17 17 April 1, 2014 letter. DR. THOMPSON: Object to form. 18 18 (Document marked for THE WITNESS: I don't know 19 19 identification as Sage Exhibit 7.) exactly what the FDA did. There are 20 BY MR. HEGARTY: 20 extraordinary gaps in time and 21 21 extraordinary issues of resources between So you've seen this before, correct? Q. 22 22 1994 petition and the 2014 response. A. I have. 23 <sup>23</sup> BY MR. HEGARTY: Q. You comment about it in your report, 24 right? 24 O. Are you an expert in the process by

Page 154 Page 156 <sup>1</sup> which FDA reviews and responds to Citizen <sup>1</sup> that's many years -- many years ago. <sup>2</sup> Petitions? Have you ever submitted materials in <sup>3</sup> connection with FDA considering a Citizen DR. THOMPSON: Object to form. 4 THE WITNESS: My expertise in <sup>4</sup> Petition? 5 how agencies communicate with public and A. No. 6 industry is sufficient to make me an Q. Have you ever drafted or been 7 expert in evaluating this letter. <sup>7</sup> involved in the drafting of FDA's responding to a <sup>8</sup> BY MR. HEGARTY: Citizen Petitions? Have you ever been involved in an A. No. <sup>10</sup> FDA review of a Citizen Petition? 10 Q. Do you know who Steve Musser is at 11 11 FDA? A. No. 12 Q. How many Citizen Petitions and FDA 12 A. No. 13 13 responses have you ever read? Q. Do you know where he went to school? 14 Probably -- well, I certainly have 14 A. 15 read the response from the 1990s on urocanic acid Q. Do you know his educational because that one is highly relevant to this case. 16 background? 17 On what? I'm sorry. Well, he's got a PhD. So I can tell 18 you he didn't go to medical school; but, no, I Urocanic acid. Α. 19 Q. don't know where he went to school. I did not --Okay. 20 U-r-o-c-a-n-i-c. I did not look him up. 21 21 Because that's rather relevant here Q. Did you try to talk to him about the <sup>22</sup> because it includes the "safety not determined" <sup>22</sup> 2014 letter? 23 <sup>23</sup> language. No. A. 24 24 I have looked at the extent to which Why not? Q. Page 157 Page 155 <sup>1</sup> Citizen's Petitions are publicly available on a I don't know him and I would have no <sup>2</sup> database. The ones relating to cosmetics do not <sup>2</sup> reason to contact him. I also, from perhaps lack <sup>3</sup> appear to be. So I've become very interested in <sup>3</sup> of experience with serving as an expert witness, <sup>4</sup> the Citizen Petition process. <sup>4</sup> decided that my reviews and research should be documentary and not involve individuals. But prior to considering these --<sup>6</sup> these issues, no, I had not looked at Citizen Did anybody instruct you as part of Q. <sup>7</sup> Petitions except in passing. You do see Citizen's <sup>7</sup> your work as an expert witness that you couldn't reach out to others and talk to them? <sup>8</sup> Petitions when you teach regulatory topics. Q. And the urocanic acid Citizen No one instructed me. It was my --<sup>10</sup> Petition was something you reviewed after being it was my working assumption. Seemed a prudent <sup>11</sup> hired as an expert in this case, correct? way to do a report. 12 12 A. Yes. Do you contend that the doctors and 13 13 scientists at the FDA involved in responding to Have you ever discussed with anyone <sup>14</sup> at FDA about FDA's handling of Citizen Petitions? <sup>14</sup> the two Citizen Petitions were not qualified to 15 No. It's very high on my list for assess the safety of talc? <sup>16</sup> when I am in contact again with FDA officials, and 16 I ---17 <sup>17</sup> I am friends with a couple of former DR. THOMPSON: Object to form. 18 <sup>18</sup> commissioners, and should I run into them, it will THE WITNESS: I express no 19 <sup>19</sup> be one of the things I will be interested in opinions on their qualifications. discussing. 20 Again, I would point out that 21 21 Q. Who are you friends with? responses to Citizen's Petitions are not 22 I'm friends with Mark McClellan and definitive responses on the underlying 23 <sup>23</sup> I'm acquaintances with Scott Gottlieb. And in the scientific questions. They are responses

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<sup>24</sup> old days, I was friends with Don Kennedy, but

to a specific request for a specific

Page 158 Page 160 1 action, in this case, for a specific one thing I will opine is that there's 2 2 warning statement. nothing in this letter that should <sup>3</sup> BY MR. HEGARTY: 3 suggest to anyone that FDA thinks that 4 Q. Well, is it your contention that if talcum powder products do not cause <sup>5</sup> FDA believed a warning was needed beyond just what ovarian cancer. <sup>6</sup> was proposed that they would have taken -- they BY MR. HEGARTY: <sup>7</sup> would not have taken this action? I'm sorry. What did you just say in DR. THOMPSON: Object to form. this last sentence? I didn't... 9 <sup>9</sup> BY MR. HEGARTY: Would you rather it read back? 10 10 Let me ask it in a different way. MR. HEGARTY: Yeah. Would you 11 Is it your contention that FDA 11 read it back, the last part of that 12 <sup>12</sup> believed a warning was needed, just not the ones response, please? 13 that were requested in the Citizen Petitions? (The reporter read the record DR. THOMPSON: Object to form. 14 on page 159 line 23 to page 160 line 5.) 15 THE WITNESS: I have no basis 15 BY MR. HEGARTY: 16 to know what FDA in some organizational 16 So is it your testimony in this case 17 sense believes on that topic. What I that FDA believes that talcum powder use causes 18 have is the regulatory provisions under ovarian cancer? 19 which a Citizen's Petition is submitted, 19 I don't know what they believe, but 20 and I have this particular response. this letter doesn't say that they believe that 21 BY MR. HEGARTY: <sup>21</sup> there is no causal association. It is simply a 22 <sup>22</sup> response, and a rather sloppily drafted response, Is it your contention that FDA <sup>23</sup> believed that there is a risk of ovarian cancer <sup>23</sup> to two Citizen's Petitions issued 20 years after <sup>24</sup> with talc use and chose to do nothing about it? <sup>24</sup> the first one. It says what it says, and I can't Page 159 Page 161 1 <sup>1</sup> give you anymore insight into the dynamics of the A. Again --2 <sup>2</sup> final text and what we have in front of us. DR. THOMPSON: Object to form. 3 THE WITNESS: -- I do not know Is it your opinion in this case that 4 anything about FDA's belief. <sup>4</sup> FDA failed to do its job with regard to responding 5 I would repeat. What we see to the two Citizen Petitions? 6 DR. THOMPSON: Object to form. in this letter, which if I were 7 7 THE WITNESS: It's my opinion supervising does not meet my standards 8 8 for clarity, is the sentence you cited, that FDA is grossly underresourced with 9 9 respect to cosmetics. quoted, which was: 10 10 "FDA did not find that the It's my opinion the Citizen's 11 11 data submitted" -- notice submitted, not Petition process needs a significant 12 12 all the data that might be available -revision, and I think this -- these two 13 13 "presented conclusive evidence." petitions and this particular response as 14 14 And then the language that I issued at this time, you know, supports 15 15 quoted back, which says: my belief that -- that the Citizen's 16 16 "Growing body of evidence to Petition process is in need of 17 17 support a possible association ... is improvement. 18 difficult to dismiss. Evidence is BY MR. HEGARTY: 19 19 sufficient -- insufficient for FDA to Well, my question wasn't very 20 20 specific. require as definitive a warning as you 21 21 are seeking." Is it your opinion in this case that 22 <sup>22</sup> FDA failed to do its job that it was tasked to do I think this is a badly 23 drafted letter. I think it is hard to <sup>23</sup> by Congress with regard to responding to these two 24 interpret and sounds rather evasive, but <sup>24</sup> Citizen Petitions?

Page 162 Page 164 1 MS. PARFITT: Objection. Johnson regarding the hazards of perineal 2 2 DR. THOMPSON: Object to form. application of talc. 3 <sup>3</sup> BY MR. HEGARTY: THE WITNESS: See, this will 4 begin to move us into kind of the core of O. And I'm still not sure you answered 5 the opinions, which is that FDA has very my question. 6 limited authority over cosmetics. FDA Is it, do you have an opinion that 7 <sup>7</sup> FDA failed to do a proper job in responding to does not supervise the self-regulatory 8 processes that cosmetics manufacturers in these two Citizen Petitions? 9 MS. PARFITT: Objection. the cosmetics industry engage in, and the 10 10 DR. THOMPSON: Object to form. fundamental obligations remain on the 11 11 manufacturers. Asked and answered. 12 12 This letter offered an THE WITNESS: All I can do on 13 13 opportunity -- I should say, these two this one, respectfully, is say, this 14 14 Citizen's Petitions offered an process is one of the -- and this outcome 15 15 opportunity for the FDA to devote more of is one of the reasons that I strongly 16 16 its resources to this particular support Congressional reform of the 17 17 cosmetics-related concern, and FDA cosmetics regulatory process. 18 <sup>18</sup> BY MR. HEGARTY: declined to take that opportunity. 19 19 You don't know who at FDA was But beyond that, I cannot 20 <sup>20</sup> involved in responding to these Citizen Petitions, opine as to their motivation as to the 21 21 pressures brought to bear on them, as to correct? 22 22 the competing uses of their resources. A. Correct. 23 23 All the things that sort of go into why You don't know what resources they O. 24 this letter is issued at this time. <sup>24</sup> devoted to respond to these Citizen Petitions, Page 163 Page 165 <sup>1</sup> BY MR. HEGARTY: <sup>1</sup> correct? My question was very specific and I I think we have a supportable <sup>3</sup> don't think you answered it. <sup>3</sup> inference that resource constraints in the My question was: Is it your opinion <sup>4</sup> cosmetic area make it very difficult for FDA to --<sup>5</sup> that FDA failed to do the job it was assigned to <sup>5</sup> to assess Citizen's Petitions and assess sua <sup>6</sup> do by Congress in responding to these two Citizen sponte actions that might be authorized by <sup>7</sup> Congress but not facilitated. <sup>7</sup> Petitions? MS. PARFITT: Objection. My question, though, is very -- is specific to this Citizen Petition response. BY MR. HEGARTY: 10 It's whether you have that opinion. Do you know the resources that FDA 11 MS. PARFITT: Objection. devoted to respond to these two Citizen Petitions 12 DR. THOMPSON: Object to form. as reflected in Exhibit No. 7? 13 13 MS. PARFITT: Question was DR. THOMPSON: Object to form. 14 14 THE WITNESS: I don't know answered. 15 15 THE WITNESS: Let me -- let the resources, but I do know, as -- as I 16 16 me try to convey accurately what my imagine you do also, that the history of 17 17 opinion is. the Citizen's Petitions, Citizen's 18 18 My opinion is that this letter Petitions are supposed to generate a 19 19 is not exculpatory of Johnson & Johnson. response within 180 days. 20 FDA issued a response to a Citizen's 20 And the, you know, earliest 21 21 Petition within its authorities, and its response to the 1994 petition was 22 22 basically, we're kind of busy, we don't response says what its response says. 23 23 It does not in any way alter have a lot of resources, and we'll get

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back to you.

the legal obligations of Johnson &

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Page 168 1 <sup>1</sup> obtained since the 1994 Workshop further suggests And then we have a 2008 2 <sup>2</sup> a health hazard and that additional work for petition and then we have a 2014 3 response, and I think simply from the <sup>3</sup> possible action is needed." 4 time course you can very reasonably infer So FDA has obviously been concerned 5 <sup>5</sup> about this for a while. In terms of an FDA that resources are insufficient to deal 6 <sup>6</sup> warning, again, the thing that -- one of the with these as they should be dealt with. <sup>7</sup> BY MR. HEGARTY: <sup>7</sup> things that distinguishes cosmetic oversight from, <sup>8</sup> say, drug oversight is that FDA's ability to Is it your opinion that FDA believes <sup>9</sup> today that a warning with regard to the risk of <sup>9</sup> require a warning is far less self-executing. <sup>10</sup> ovarian cancer is needed on talcum powder FDA does not require -- does not <sup>11</sup> directly regulate the label or labeling of a lot products? 12 DR. THOMPSON: Object to form. <sup>12</sup> of aspects of cosmetics; and if FDA wishes to 13 13 require a warning, it has legal authority to do THE WITNESS: I think it is 14 so, but it has to do it through notice and comment clear that the -- that pending changes in 15 rulemaking at significant expense and a leadership or new statements from FDA 16 leadership that FDA believes that significant degree of legal uncertainty. 17 cosmetics regulation needs to be So, you know, I am willing to 18 improved, and which would support an <sup>18</sup> suggest that FDA institutionally sees some 19 significant concerns about causal relationships inference that the things that FDA has 20 between perineal talc and ovarian cancer, but the been involved in with cosmetics 21 <sup>21</sup> regulatory system is not set up for FDA to regulation are things that they do not 22 <sup>22</sup> vindicate those concerns, which is another reason think are adequate to protect the public. <sup>23</sup> BY MR. HEGARTY: why your client should have. 24 24 Q. And my question is specific as it Q. You have not talked to anybody at Page 169 Page 167 <sup>1</sup> relates to talcum powder products and ovarian <sup>1</sup> FDA with regard to talcum powder use or talcum powder products and ovarian cancer, correct? <sup>2</sup> cancer risk. Is it your opinion that FDA believes 3 A. I look forward to doing so. <sup>4</sup> that a warning is needed today on talcum powder Q. Well, have you talked to anybody? products and ovarian cancer risk? A. 6 DR. THOMPSON: Object to form. 6 Paragraph 39 of your report, which Q. 7 THE WITNESS: So this -- may <sup>7</sup> is on page 6, the second sentence refers states 8 8 I refer to a document we've previously that: 9 discussed? "Asbestos when present in talcum <sup>10</sup> BY MR. HEGARTY: powder product is an adulterant because it is 11 11 hazardous to human health." Does that answer the question? O. 12 12 A. Yes. Do you see where I'm reading? 13 13 I do. 0. Sure. A. 14 14 So if we -- if we go back to -- or One of the materials you cite there <sup>15</sup> did you hand it back or do you still have it? The is a document, is an NIH document entitled <sup>16</sup> 1998 FDA internal review. That document includes "Asbestos Worker and Employer Guide to Hazards and <sup>17</sup> -- here it is. This one that we looked at Recommended Controls." <sup>18</sup> (indicates). 18 Do you see that? 19 19 That document includes a statement I'm -upfront. Again, it's not a statement of FDA 20 DR. THOMPSON: What page are 21 <sup>21</sup> policy, but it is a statement specifically on talc you on, please? <sup>22</sup> that pointing out FDA's Workshop says: 22 MS. PARFITT: Page 6 of the 23 "Perineal talc has been linked to report. <sup>24</sup> increased risk of ovarian cancer. Additional data 24 THE WITNESS: Sorry. I'm not

Page 170 Page 172 1 seeing that particular -workplace exposure documents, certainly. 2 <sup>2</sup> BY MR. HEGARTY: DR. THOMPSON: Okay. 3 You're, of course, familiar with MS. PARFITT: Paragraph 39. O. <sup>4</sup> BY MR. HEGARTY: NIH, correct? Yeah, if you look at --A. Yes. 6 6 And you're familiar with the NCI, I'm not seeing that particular A. Q. <sup>7</sup> right? paragraph. 8 -- 39 at the end, footnote 9 says A. Yes. Q. 9 9 And NCI is the federal government's NIOSH. O. 10 It's got the NIOSH and OSHA primary health agency on cancer research, correct? A. I would have -- that's -- that's a material, which is where why the Material Safety Data Sheets get revised -strong statement, but for the federal government, 13 13 Q. Right. That document -yes. 14 14 -- to give talc exposure. Q. Have you ever had any dealings with A. 15 15 NCI? I'm sorry. Q. 16 That document is "Workplace Exposure Institutionally, no. Indirectly, I to Asbestos," correct? 17 <sup>17</sup> have a very wide circle of contacts, and I serve on a number of advisory committees, and 18 Yes. A. 19 Did you read that document? undoubtedly there's been overlap with -- with NCI Q. 20 No. I read various things that over the years. 21 21 referenced that document. If you go back and look at this 22 Do you understand that document is <sup>22</sup> Exhibit No. 5, the literature materials we've been talking -- we were talking about earlier? 23 about occupational exposure to asbestos? 24 24 A. I understand that document is about A. Uh-huh. Page 171 Page 173 <sup>1</sup> occupational exposure to asbestos. I don't recall You look over at page 6 of that document. Tell me when you're at page 6. <sup>2</sup> the details of all these documents, but I have <sup>3</sup> noticed that several of the documents that discuss 3 A. I'm at page 6. <sup>4</sup> occupational exposure also at least have brief You refer in that document to "NCI <sup>5</sup> Snapshot of Ovarian Cancer." It's the very top of <sup>5</sup> mention of nonoccupational exposure risks. Do you know that that document does the page. <sup>7</sup> not discuss talcum powder use? You see that? I would -- I would have to -- I Yes, and it doesn't have the <sup>9</sup> would have to review that document to confirm snapshot exactly. I have -- I have an NCI document in front of me that is actually a D <sup>10</sup> that; but, again, remember the assertion is about <sup>11</sup> the dangers of asbestos. To the extent that exhibit. It's a defense exhibit. 12 <sup>12</sup> asbestos is present in talcum powder, it is by We're going to get to that. 13 <sup>13</sup> FDA's own statement and by other sources But in terms of the document you reference in your materials, it's this "Snapshot <sup>14</sup> conclusively an adulterant. 15 of Ovarian Cancer," right? But you're not -- I'm sorry. Q. 16 It's not dose-dependent. It's not 16 A. 17 dose-dependent. It's not route-dependent. It is O. Did you read that document? 18 simply an adulterant. A. It was made available. I don't 19 But you understand that the support 19 recall I read your defense exhibit word for word. you're citing for that statement is a document 20 You don't cite that defense exhibit Q. <sup>21</sup> that refers to "Workplace Exposure to Asbestos," in your materials? <sup>22</sup> one of the supporting documents? 22 A. You're right. 23 23 DR. THOMPSON: Object to form. Did you look at it in preparing your Q. 24 THE WITNESS: I have seen <sup>24</sup> report?

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- A. Did I look at the?
- <sup>2</sup> Q. The document -- well, did you look <sup>3</sup> at the NCI PDQ that you reference as a defense <sup>4</sup> exhibit in preparing your report?
- A. It may have been brought to my
   attention. Oh, yes. I did look at it in
   preparing my report, yes.
  - Q. And why didn't you reference it?
- <sup>9</sup> A. I don't know. If that -- if that was an oversight, I apologize.
- Q. You agree you didn't even reference it in the materials that you reviewed, right?

  MS. PARFITT: Objection.

Form.

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THE WITNESS: Again, I don't -- I would have to verify that but...

MR. HEGARTY: I'll mark as
Exhibit No. 8 what I think is the same -THE WITNESS: I saw -- I saw
a reference to -- to that defense exhibit
perhaps in this other more general
document, and I specifically requested
the defense exhibit.

(Document marked for

A. I will take your word for that.

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<sup>2</sup> Q. Do you recall referencing it in the <sup>3</sup> body of the report?

- A. I don't think I did.
- <sup>5</sup> Q. And do you recall any -- do you see <sup>6</sup> any reference in the list of materials that you <sup>7</sup> reviewed to this document?
- A. No. I do remember it well and I've looked at it several times, and I have, you know, I have evaluated it and did not think it warranted direct inclusion in the report.
- Q. So you didn't -- is it your testimony that you do not believe this document, the NCI PDQ and what it says about talc and ovarian cancer, is a relevant document to your opinions in this case?
  - A. I believe -DR. THOMPSON: Object to form.
    THE WITNESS: I believe it is
    relevant and I considered it. I did not
    think it was sufficiently important to
    reference directly. Be happy to discuss
    why.

<sup>24</sup> BY MR. HEGARTY:

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identification as Sage Exhibit 8.)

<sup>2</sup> BY MR. HEGARTY:

- Q. I've marked as Exhibit 8 I think is
   the same document you've been looking at. It's
   the --
- <sup>6</sup> A. Yes.
- Q. -- July 8, 2021 NCI Physician Data
   Ouery.
- <sup>9</sup> Is this the same document you were <sup>10</sup> referencing before?
- A. Yes. Yours is printed two-sided so it seems smaller.
- Q. Again, then you think -- strike that.
- Your testimony is that you did review this document prior to completing your expert report; is that correct?
  - A. I believe so.

DR. THOMPSON: Object to form. THE WITNESS: I believe so.

<sup>21</sup> BY MR. HEGARTY:

Q. And you also agree you make no reference to it anywhere in your expert report, right?

- Q. Well, did you find this document on your own or did plaintiffs' counsel provide it to you?
- A. I asked for this document because I
- <sup>5</sup> believed it was either -- either I saw it or it
- <sup>6</sup> was referenced in that Facts About Talc document
- <sup>7</sup> collection that we were talking about before.
- $^{\rm 8}\,$  Because I remember specifically asking, as I was
- <sup>9</sup> asking for things that appeared to support the
- <sup>10</sup> defense's arguments, I asked specifically about
- <sup>11</sup> the NCI document, and that's how I got the NCI
- <sup>12</sup> document.
- Q. Prior to reading something about the
- 14 NCI PDQ document, Exhibit No. 8, had you ever been
- 15 aware that NCI puts out Physician Data Query
- 16 documents like this?
- A. In passing, probably, but I wouldn'thave had a need for them in clinical practice.
- Q. If you turn over to page 19 of 20 in
- 20 this document and the pages that are at the
- 21 bottom --
- <sup>22</sup> A. Yes.
- Q. -- that reference 19 of 20, it says
- <sup>24</sup> that this PDQ in the -- let me back up.

| se | 3:16-md-02738-MAS-RLS <sub>W</sub> <u>:</u>                     | ද්දි <sub>ලිදු</sub> , Files                                     |
|----|---|--|
|    | Page 178  |  |
|    | Under the purpose of this summary at                            | <sup>1</sup> 20, under section                                   |
|    | <sup>2</sup> the top, it says that this is a summary for health | <sup>2</sup> A. Hold on.   |
|    | <sup>3</sup> professionals let me read it specifically.         | <sup>3</sup> Q. I'm sorry.                                       |
|    | <sup>4</sup> "This PDQ cancer information summary               | <sup>4</sup> A. I have to go back to that. Yeah.                 |
|    | <sup>5</sup> for health professionals provides comprehensive    | <sup>5</sup> Q. Under the section Factored with                  |
|    | <sup>6</sup> peer-reviewed evidence-based information about     | <sup>6</sup> Inadequate Evidence of Association Risk of          |
|    | ovarian, fallopian tube, and primary peritoneal                 | <sup>7</sup> Ovarian, Fallopian Tube, and Primary Peritoneal     |
|    | 8 cancer."  | <sup>8</sup> Cancer, they specifically refer to perineal talc    |
|    | 9 Did I read that correctly?                                    | <sup>9</sup> exposure, correct?                                  |
| 1  | A. Peritoneal cancer prevention but                             | <sup>10</sup> A. Correct.  |
| 1  | <sup>1</sup> Q. Peritoneal cancer prevention.                   | Q. The first line of that summary says:                          |
| 1  | And it goes on to say:  | "The weight of evidence does not                                 |
| 1  | <sup>3</sup> "It is intended as a resource to                   | <sup>13</sup> support an association between perineal talc       |
| 1  | <sup>4</sup> inform and assist clinicians who care for cancer   | <sup>14</sup> exposure and an increased risk of ovarian cancer." |
| 1  | <sup>5</sup> patients."   | Correct?   |
| 1  | 6 Correct?  | A. Yes, that's their view expressed in                           |
| 1  | A. Correct.   | <sup>17</sup> this particular                                    |
| 1  | <sup>8</sup> Q. Then it goes down under the section             | <sup>18</sup> Q. And they  |
| 1  | <sup>9</sup> Reviewers and Updates that says:                   | <sup>19</sup> A summary.   |
| 2  | This summary is reviewed regularly                              | Q. They don't they say there's not                               |
| 2  | <sup>1</sup> and updated as necessary by the PDQ Screening and  | <sup>21</sup> even association in this statement, correct?       |
| 2  | <sup>2</sup> Prevention Editorial Board, which editorial        | <sup>22</sup> A. Now   |
| 2  | <sup>3</sup> independent of the National Cancer Institute       | DR. THOMPSON: Object to form.                                    |
| 2  | <sup>4</sup> (NCI)."  | THE WITNESS: again you are                                       |
|    | Page 179  | Page 181   |
|    | <sup>1</sup> Correct?   | <sup>1</sup> correctly saying. They say in slightly              |
|    | <sup>2</sup> A. Yes.  | stylized form, the weight of evidence                            |
|    | Q. Then it goes on to say:                                      | does not support an association and that                         |
|    | 4 "This summary reflects an                                     | results from the various case-controlled                         |
|    | <sup>5</sup> independent review of literature and does not      | and cohort studies are inconsistent, and                         |
|    | <sup>6</sup> represent a policy statement of NCI or the         | then they argue the points back and                              |
|    | National Institutes of Health (NIH)."                           | <sup>7</sup> forth.  |
|    | 8 Correct?  | 8 It is this is to me  |
|    | <sup>9</sup> A. Correct.  | <sup>9</sup> representative of much of the discussion            |
| 1  | Q. Then it goes on to describe that:                            | that I have seen in other sources. There                         |
| 1  | <sup>1</sup> "The board members review recently                 | are, you know, several studies here that                         |
| 1  | <sup>2</sup> published articles each month to determine whether | they cite that show confidence intervals                         |
| 1  | <sup>3</sup> an article should" and then it describes what      | that are all above 1.  |
| 1  | 4 their they can do with it, with the article,                  | Their, you know, so, again,                                      |
| 1  | <sup>5</sup> discussing it, citing the text, replacing it with  | their conclusion and their categorization                        |
| 1  | <sup>6</sup> an updated article, correct?                       | is based on what they consider                                   |
| 1  | A. Certainly. It reminds me very much                           | inconsistencies and how they weight                              |

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inconsistencies and how they weight particular sort of dose-response style associations, or lack thereof.

There's nothing in this that is sort of new information to me beyond the other studies and syntheses that I have -- I've read and from the language you yourself quoted.

<sup>18</sup> of loosely electronic scientific American medicine

<sup>19</sup> chapters that were published for many years and I

<sup>20</sup> subscribed to. I don't subscribe anymore, but the

<sup>22</sup> clinical guidance and you provide a mechanism

Then if we turn over to page 13 of

<sup>21</sup> notion is that you want to have some current

<sup>23</sup> for -- for updates periodically.

Q.

This is an editorial exercise with an NIH-funded publication resource. It is not an official clinical guideline. It is not an official policy statement. One could speculate if you ask

the authors of this what they would advise their own patients regarding perineal application of talcum powder, I don't know it would be that "don't worry about it" is the response that you'd get.

This is exactly the sort of material that I think is highly relevant, but is also, first of all, embedded in -in a whole set of professional relationships and traditions between clinical physician practice and government bodies that is really tangential to my opinions about a manufacturer's self-regulatory obligations for cosmetics.

## <sup>21</sup> BY MR. HEGARTY:

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22 Assume for purposes of my question -- and it's a hypothetical -- that this <sup>24</sup> statement is true that the weight of evidence does

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<sup>1</sup> not support an association between perineal talc <sup>2</sup> exposure and an increased risk of ovarian cancer.

<sup>3</sup> So assume that's true.

Would it still be your opinion that <sup>5</sup> talcum powder is unsafe?

DR. THOMPSON: Object to form. 7

THE WITNESS: It would still 8 be my opinion that Johnson & Johnson has

9 not complied with its regulatory

10 obligations regarding information, and 11

there's a whole lot of ambiguities in

12 this particular statement.

## 13 BY MR. HEGARTY:

14 Again, assume for purposes of my question that this -- that the statement I just read to you is true.

17 Is it still your opinion that talcum powder products should contain a warning about the 19 risk of ovarian cancer?

20 DR. THOMPSON: Object to form. 21 THE WITNESS: If this

22 statement were true as written, it is 23 still my opinion that Johnson & Johnson 24

is required to provide consumers with

information it does not currently

2 provide.

#### <sup>3</sup> BY MR. HEGARTY:

And what would that information be if this statement is true?

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At a minimum, the statement -- the <sup>7</sup> statement that safety has not been determined. <sup>8</sup> Because, again, this is, you know, a weight of evidence, inconsistencies, and things that they cite certainly do not substantiate the safety

<sup>11</sup> of -- of talcum powder products.

Moreover, you know, the exact contents of talcum powder products are not really dealt with in this particular report, and I don't really know what assumptions they've made.

16 Have you told me in your responses to the last few of my questions why you don't -did not cite this document in your report?

I --

DR. THOMPSON: Object to form. THE WITNESS: Yes. I've told you that I reviewed it, and I did not find that it added information in ways that would modify my opinion.

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## <sup>1</sup> BY MR. HEGARTY:

Is that what your standard was for <sup>3</sup> citing material is whether it would modify your opinions?

DR. THOMPSON: Object to form.

THE WITNESS: One's -- one formulates one's opinions and modifies one's opinions in light of new evidence.

If this is a piece of evidence I'm being presented with, if it is information that I think needs to be conveyed to the audience of my report on its own, I might include it.

But in terms of, is it altering my then present analysis, if it doesn't alter it, I have no other reason to cite it, and that is simply a Bayesian approach to formulating and modifying conclusions.

If you're suggesting that somehow I had decided in advance what my conclusions are, I would strongly disagree.

<sup>24</sup> BY MR. HEGARTY:

Page 186 Page 188 1 0. Well, I think the reader will <sup>1</sup> report that are not policy statements, right? 2 <sup>2</sup> interpret that, but let me point this out. A. You did cite to IARC in your report, 3 Q. You cite to medical literature, 4 correct? right? A. Yes. A. Yes. 6 6 And what it said about talcum powder Not a policy statement, is it? O. Q. use and ovarian cancer, correct? A. A. Yes. O. So this document, though, you chose, 9 You did cite to FDA in your report unlike some other articles that you cited, not to Q. <sup>10</sup> and what it said about talcum powder use and cite, correct? 11 ovarian cancer, correct? DR. THOMPSON: Object to form. 12 12 A. Yes. THE WITNESS: I didn't 13 13 0. Those -- and you do cite to NIOSH affirmatively decide not to cite it. It 14 <sup>14</sup> and what it says about asbestos exposure and risk, did not rise to the level where I felt 15 <sup>15</sup> correct? induced to cite it. 16 16 Indirectly in the footnote that you MR. HEGARTY: Let me show you 17 <sup>17</sup> read. I don't -- I don't emphasize a discussion what I've marked as Exhibit No. 9. <sup>18</sup> of the occupational hazards here, though I -- I do 18 (Document marked for 19 think that the NIOSH conclusions and the way in 19 identification as Sage Exhibit 9.) <sup>20</sup> which the talc mining companies responded to them 20 BY MR. HEGARTY: <sup>21</sup> in terms of worker protection are informative in 21 This is the PDQ Screening and <sup>22</sup> Prevention Editorial Board for the PDQ that we <sup>22</sup> this case. 23 marked as Exhibit No. 8. So you cite to IARC, you cite to <sup>24</sup> FDA, you cite to NIOSH, but you don't cite to NCI, Have you seen this list of board Page 187 Page 189 <sup>1</sup> correct? 1 members? 2 A. I have not. I have a medical school Again --3 DR. THOMPSON: Object to form. classmate on the list. 4 THE WITNESS: Again, I really Q. Who is that? 5 5 have to be clear that this is a A. Joann Elmore. 6 NCI-supported journal that follows a 6 She's got a Master of Public Health, Q. 7 perfectly reasonable clinical update <sup>7</sup> right? 8 8 process. It is not a statement of the A. Yes, she does. 9 NCI, and the language that you read Q. You do not have a Master of Public 10 <sup>10</sup> Health, right? confirmed that. 11 <sup>11</sup> BY MR. HEGARTY: A. I do not. 12 12 So it's your opinion that a reader O. And Joann Elmore, do you respect her 13 looking at your report would not be interested in 13 as an epidemiologist? what the NCI PDQ has to say about talcum powder As an epidemiologist? I would have 15 to go back and talk to her in a few years, but I use and ovarian cancer? 16 MS. PARFITT: Objection. <sup>16</sup> would have to go back and see what her work is. 17 DR. THOMPSON: Object to form. But, yes, I respect her. I respect everybody on 18 THE WITNESS: It's my opinion <sup>18</sup> this list. 19 19 that I might be misleading a reader of my But that's not the same thing as 20 report to suggest that an NCI -- that saying that this particular statement of the 21 this particular NCI document is a policy <sup>21</sup> literature is in any sense definitive, in any 22 statement of NCI, which it's not. <sup>22</sup> sense a policy statement, and I think on its own 23 terms an informed reader would -- would not simply 23 BY MR. HEGARTY: 24 <sup>24</sup> take their categorization at face value. You cite to other material in your Q.

Page 190 Page 192 As I said, I suspect that if you 1 Q. Do you know who the CDC is? 2 <sup>2</sup> asked the individuals who actually wrote this A. I do. <sup>3</sup> article what they would advise their own patients, 3 O. Do you know who the SGO is, the <sup>4</sup> I don't think "don't worry about it" would be the <sup>4</sup> Society of Gynecologic Oncologists? <sup>5</sup> answer from all of them, but that's just my I never heard it with the acronym. <sup>6</sup> I've heard of the Society of Gynecologic <sup>6</sup> professional opinion. Do you know any of the other Oncologists. individuals on this list? Q. Do you know who ACOG is, the 9 American College of --A. Hmm. 10 10 I know who ACOG --(Reviews document.) 11 11 -- Obstetricians and Gynecologists? I suspect I know who David Q. 12 Ransohoff's father was but, no. 12 Sorry to interrupt you. 13 13 Did you contact any of these Yes, I know who ACOG is. 14 14 individuals about the NCI PDQ? Did you review their list of risk 15 <sup>15</sup> factors for ovarian cancer? Α. No. 16 O. Did you even look at this editorial 16 It's possible I did. I don't -- I 17 board before preparing your report? don't recall. If I -- if I had been looking 18 casually in my very initial investigations before A. No. 19 And the board members, as it says in deciding whether or not to offer an opinion in this case, ACOG would have been the household name this document, represents -- represent the field <sup>21</sup> of oncology, cancer prevention, cancer screening, <sup>21</sup> for me, and if I went to one place, that's where I <sup>22</sup> would have gone. But I don't know that I found <sup>22</sup> hematology, radiology, urology, statistics, epidemiology, and economics, correct? <sup>23</sup> anything. 24 24 O. Do you know that ACOG does not list A. That's what it says. Page 191 Page 193 You don't represent any of those <sup>1</sup> talc as a risk factor for ovarian cancer? <sup>2</sup> fields, correct? DR. THOMPSON: Object to form. 3 3 DR. THOMPSON: Object to form. THE WITNESS: Again, I can't 4 THE WITNESS: I certainly recall. All of this, you know, is in 5 5 have expertise in cancer prevention from some sense tangential to, you know, the 6 the work I've done. I have expertise in fundamental questions in my opinion. 7 <sup>7</sup> BY MR. HEGARTY: cancer screening from the work I've done. 8 I have some statistical expertise, some Before being hired by the 9 plaintiffs' lawyers to work on this case, you had epidemiological expertise, and a whole 10 10 lot of economic expertise. never written anything about talc, correct? 11 11 BY MR. HEGARTY: A. Correct. 12 12 Q. Q. Okay. You never commented on talc, 13 Do I practice any of these as my 13 correct? 14 14 dominant profession? No. Α. Correct. 15 15 Before being hired by plaintiffs' Is it your contention that the 0. <sup>16</sup> editorial board members did not properly review <sup>16</sup> lawyers in this case, you had never written anything about any cosmetic product, correct? the medical literature to come to the statements 18 that they set out in the PDQ we marked as Exhibit DR. THOMPSON: Object to form. <sup>19</sup> No. 8? 19 THE WITNESS: Anything that 20 DR. THOMPSON: Object to form. 20 was solely a cosmetic product? 21 THE WITNESS: I have no such <sup>21</sup> BY MR. HEGARTY: 22 22 opinion, and I think it is tangential to O. Correct. 23 23 my opinions in this case. No. A. <sup>24</sup> BY MR. HEGARTY: 24 O. Before being hired to testify on

Page 196 1 <sup>1</sup> behalf of plaintiffs in this case, you had never activities and disclosure obligations, 2 <sup>2</sup> written anything about asbestos, correct? and also about First Amendment claims DR. THOMPSON: Object to form. 3 involved in government regulation of 4 THE WITNESS: That's probably information. 5 correct. I'd have to go see. I suspect BY MR. HEGARTY: 6 that in articles that I've written, I've Q. And my question is specifically as 7 it relates to a cosmetic product. made references or comparative references 8 to asbestos litigation. It would be Again, it's not that I can recall in 9 unavoidable given how much regulatory the sense it would have been in passing. 10 health and safety work I've done. 10 Have you ever written anything in 11 the published medical literature or the literature BY MR. HEGARTY: 12 I think we did a search for your -- let me -- let me ask it a different way. 13 name and asbestos and didn't come up with Have you ever published an article <sup>14</sup> or anything, any published document that talks anything. 15 about ovarian cancer? A. Good to know. Thank you. (Laugh). 16 Do you recall ever talking about 16 A. Q. Hmm. 17 17 asbestos in any article you've ever written? DR. THOMPSON: Object to form. 18 18 THE WITNESS: Again, not that Α. I don't. 19 19 DR. THOMPSON: Object to form. I can recall and probably not. 20 20 BY MR. HEGARTY: THE WITNESS: I'm pretty sure 21 21 I've done it in passing because, as I Have you ever spoken to an audience 22 22 said, you know, if you're writing about about talcum powder? 23 23 sort of major product-related personal A. No. 24 24 injury litigation, chances are you made Q. Have you ever spoken to an audience Page 197 Page 195 <sup>1</sup> about asbestos? reference to asbestos. But if you can't 2 find it, then it may not exist. A. <sup>3</sup> BY MR. HEGARTY: 3 O. Have you ever spoken to an audience Have you ever written anything in about heavy metals? 5 5 the published literature about fragrance? A. No. 6 6 Q. A. No. Fragrances? 7 How about heavy metals? A. I have never spoken to an audience Q. 8 about fragrances. A. 9 Have you ever written anything in 9 Q. Q. Have you ever spoken to an audience <sup>10</sup> the published literature about the manufacturers 10 about ovarian cancer? 11 who make cosmetic products? As it relates to In passing, yes. A. 12 their manufacture of cosmetic. Q. How have you done so in passing? 13 13 About -- so I would use ovarian Oh. No. 14 DR. THOMPSON: Object to form. cancer often as an example for my regulatory 15 BY MR. HEGARTY: theory classes on risk framing issues, and 16 Have you ever written anything on specifically telling the story of Gilda Radner's the development, manufacture, marketing, or sale ovarian cancer and the misperception that many --17 <sup>18</sup> that the general public took away from that that of any cosmetic product? 19 19 ovarian cancer was somehow preferentially a DR. THOMPSON: Object to form. 20 THE WITNESS: Not that I can <sup>20</sup> disease of younger women when it's actually a 21 <sup>21</sup> disease of older women. So it would have been a recall. I have to answer it that way 22 <sup>22</sup> common anecdote I would use. because when we're talking about 23 marketing activities, I write a whole lot I actually teach a whole lot about 24 about relationship between marketing <sup>24</sup> cancer prevention and -- and cancer screening

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<sup>1</sup> tests in my regulatory theory classes every time I <sup>2</sup> teach them.

- Have you ever spoken to an audience <sup>4</sup> about the causes of ovarian cancer?
- No. A.
- 6 Have you ever taught any courses Q. where talc was discussed?
- No. A.
- 9 Q. Where asbestos was part of the 10 course?
- 11 Again, not that I can recall, but 12 it's a common example of, you know, I think probably in discussing Stephen Jay Gould's <sup>14</sup> non-asbestos mesothelioma.
- 15 Q. You're not an oncologist, correct?
- 16 A. Correct.
- 17 O. You're not a gynecologist, correct?
- 18 A. Correct.
- 19 Q. You're not an expert in the overall
- 20 field of ovarian cancer, correct?
- 21 I'm not a clinical or molecular expert, cellular expert in ovarian cancer, no.
- You're not an expert on the risk
- <sup>24</sup> factors for ovarian cancer, correct?

<sup>1</sup> but ovarian cancer, no.

- You never treated a patient for
- ovarian cancer, correct?
  - I'm not sure of that, but it
- wouldn't have been the primary diagnosis. I
- probably have treated a patient who had prior -previously been diagnosed with ovarian cancer.

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- My question, though, is: Have you ever treated a patient for her ovarian cancer?
  - A.
- 11 O. Have you ever treated a patient for 12 mesothelioma?
  - A.
- 14 Q. Have you ever treated a patient for 15 peritoneal mesothelioma?
- 16 A.
- 17 O. Have you ever diagnosed a patient
- with an asbestos-related disease?
- 19 That's really interesting.
  - I did a lot of work at the Palo Alto
- <sup>21</sup> VA hospital, and it was a World War II era patient <sup>22</sup> base.
- 23 Not that I can recall.
  - Q. Do you know what asbestosis is?

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- I evaluate risk factors in -- for
- <sup>2</sup> cancer in a lot of the work I do. So I haven't
- <sup>3</sup> applied that expertise to ovarian cancer; but,
- <sup>4</sup> again, I reiterate that I'm not offering a medical
- <sup>5</sup> opinion or epidemiological opinion on causation.
- Can you cite for me the risk factors <sup>7</sup> for serous invasive ovarian cancer?
  - DR. THOMPSON: Object to form.
- 9 THE WITNESS: Off the top of 10 my head, no. I, you know, can suggest 11 that some of them have to do with parity.
- 12 Some of them have to do with various
- 13 exposures. Some of them probably have to 14
  - do with family history.
    - But I would have to look them up, as I would look up risk factors for pretty much anything.
- BY MR. HEGARTY:
- 19 You never performed any research on 20 ovarian cancer, correct?
- 21 A. No.

15

16

17

24

- 22 You've never been the doctor who
- 23 diagnosed a patient's ovarian cancer, correct?
  - I have diagnosed patients' cancers,

- A. Yes.
- 2 Q. Do you know what pleural plaques 3 are?
- I can -- I can imagine what pleural plaques are. I don't -- don't know if I've used
- that term in a clinical setting.
- Do you know what ferruginous bodies Q. 8 are?
- 9 A.

11

16

19

- Apparently not because I'll need you 10 to --
  - Q.
  - Ferruginous bodies. Do you not?
- 12 Ferruginous? I do not. A.
- 13 If a woman needed to be evaluated
- for a possible case of ovarian cancer, no one
- would refer them to you, right?
  - That would be correct.
- 17 O. If someone did, you would refer them
- to someone else, right?
  - With alacrity. Α.
- 20 No one has ever sought out your
- <sup>21</sup> consultation regarding a patient with ovarian 22
- cancer, correct?
- No one -- as we've established
- <sup>24</sup> repeated -- repeatedly, I do not have an active

<sup>1</sup> clinical practice. I do not have sort of subfield <sup>2</sup> specialization in gynecology or obstetrics or in

<sup>3</sup> oncology; but in the course of my teaching and

- <sup>4</sup> research and scholarly work, I encounter all of
- <sup>5</sup> these diseases and tests, symptoms, risk factors <sup>6</sup> and, frankly, access to and cost of treatment.
- You never came to the opinion that asbestos caused any patient's ovarian cancer, correct?
- 10 In this -- in this instance, I will <sup>11</sup> rely on multiple statements about asbestos as a 12 risk factor for ovarian cancer, as for other cancers.
- 14 No. My question is very specific. O. 15 You never came to the opinion that <sup>16</sup> asbestos caused any particular patient's ovarian cancer, correct?
- 18 That would follow directly from not having treated a patient for ovarian cancer.
- You've never discussed the risk factors of ovarian cancer with a patient, correct?
- 22 Correct.
- 23 You've never talked to a patient Q. <sup>24</sup> about talcum powder use, correct?

When is the last time you went to a <sup>2</sup> meeting of a medical society?

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Probably about three years ago and <sup>4</sup> sat in on a whole variety of interesting radiologic sessions, in addition to the one that I

<sup>6</sup> spoke out on on policy issues. I have a basic

<sup>7</sup> principle that I don't just go in and out when I speak, and I always sit and listen to things.

Have you ever been involved in any published article related to the female reproductive tract?

12 A. No. 13 DR. THOMPSON: Object to form. <sup>14</sup> BY MR. HEGARTY:

15 In fact, you never published a medical article, correct?

Not correct. I have published medical articles.

19 You published medical article about the clinical practice of medicine?

21 Yes. When I -- when I was in <sup>22</sup> medical school, I was lead author on articles <sup>23</sup> about intensive care practice and about urologic <sup>24</sup> practice. They emphasized the outcomes and the

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A. Not -- not that I can recall.

Have you ever recommended to any <sup>3</sup> physician that they advise against talcum powder 4 use?

5 A. No.

Have you ever told anybody to stop <sup>7</sup> using talcum powder?

I certainly would now.

My question is: Prior to today, Q.

<sup>10</sup> have you ever told any person to stop using talcum 11 powder?

12 No. I have evaluated mentally my A. own brief talcum powder use wondering.

You don't belong to any medical organizations currently, do you?

16 A.

17 Q. What medical organization do you <sup>18</sup> belong to?

I'm an AMA member and have been <sup>20</sup> forever. I'm trying to think what else that would <sup>21</sup> qualify as a medical organization. But, I mean, <sup>22</sup> again, I'm a -- I'm an elected member of the

<sup>23</sup> National Academy of Medicine. So I think I have <sup>24</sup> medical bona fides.

<sup>1</sup> cost-related care choices. They weren't

generating clinical practice guidelines, if you

<sup>3</sup> will; but, yes, they are -- they were

<sup>4</sup> fundamentally clinical articles.

And none of those articles had <sup>6</sup> anything to do with the reproductive tract, female <sup>7</sup> reproductive tract, correct?

That's correct. I mean, obviously the urologic article had to do with male reproductive tract or reproductive organs.

You're not an expert in talc, 12 correct?

13 DR. THOMPSON: Object to form. 14 THE WITNESS: Could you ask 15 that in a way that I know what -- what 16 piece of the discipline you're interested 17 in?

BY MR. HEGARTY:

19 Well, would you call yourself an 20 expert in talcum powder?

A. No.

21

22

DR. THOMPSON: Object to form. THE WITNESS: No.

<sup>24</sup> BY MR. HEGARTY:

Page 206 Page 208 Q. Would you call yourself an expert in Have you ever conducted an <sup>2</sup> epidemiologic study? <sup>2</sup> asbestos? A lot of the research that I do uses DR. THOMPSON: Object to form. THE WITNESS: No. <sup>4</sup> the quantitative techniques that are common in <sup>5</sup> epidemiology. I haven't done -- I haven't been an <sup>5</sup> BY MR. HEGARTY: <sup>6</sup> author or coauthor of something that is sort of a Can you name the 6 types of <sup>7</sup> regulated asbestos? primary epidemiological study. DR. THOMPSON: Object to form. Have you ever published a review of 9 THE WITNESS: Offhand, no. I epidemiologic evidence? 10 can pronounce them, I believe, you know. 10 A. No. <sup>11</sup> BY MR. HEGARTY: 11 O. You're not an expert on the testing 12 Can you tell me the difference <sup>12</sup> of -- of talc for the presence of asbestos, <sup>13</sup> between an amphibole and a serpentine form of correct? 14 asbestos? DR. THOMPSON: Object to form. 15 15 DR. THOMPSON: Object to form. THE WITNESS: Correct. 16 THE WITNESS: BY MR. HEGARTY: 17 17 Mineralogically, no. I know those are You're not an expert in geology, 18 two of the forms. 18 correct? BY MR. HEGARTY: 19 Again, I have preparation and 20 <sup>20</sup> interest in geology. So there are areas of You know what the most commercially geology that I have far more than lay credentials 21 used asbestos was? 22 DR. THOMPSON: Object to form. with respect to. 23 23 THE WITNESS: I have read --Would you call yourself a geologist? O. 24 24 read that. I don't recall. A. No. Page 207 Page 209 <sup>1</sup> BY MR. HEGARTY: You're not an industrial hygienist, Q. Did you analyze the toxicities of correct? asbestos across the various forms? Correct, but, again, there is A. DR. THOMPSON: Object to form. <sup>4</sup> considerable overlap; but I have experience with 5 THE WITNESS: No, but nothing OSHA regulations and practices. 6 in my opinion relates to my having done Q. You're not an expert in Johnson's <sup>7</sup> Baby Powder, are you? any of this personally. 8 BY MR. HEGARTY: DR. THOMPSON: Object to form. 9 9 Q. You're not a toxicologist, correct? THE WITNESS: I believe it 10 10 I am -- correct. was applied to me in early childhood but, 11 11 You're not an expert in fragrances, Q. 12 correct? 12 BY MR. HEGARTY: 13 A. Correct. Do you know where Johnson & Johnson 14 <sup>14</sup> has mined its talc for its Johnson's Baby Powder You're not a genesis -- geneticist, Q. over the years? correct? 16 16 I'm not a geneticist. I have read that in connection A. 17 Q. Not a mineralogist, correct? with -- with these issues. I had no prior 18 I took two geology classes in knowledge of that. 19 19 college, but I'm not a mineralogist. Do you know where Johnson & Johnson 20 You've had no formal epidemiologic <sup>20</sup> currently obtains its talcum powder for its baby training, correct? powder products? 22 For the products it doesn't sell I've had some epidemiologic training <sup>23</sup> in medical school as, you know, consequence to <sup>23</sup> here? I don't know. <sup>24</sup> receiving a medical school. O. Well, you understand that Johnson's

Page 212 <sup>1</sup> Baby Powder is sold outside the United States and <sup>1</sup> don't think I've ever spoken at one at the request <sup>2</sup> Canada --of a plaintiff's lawyer. 3 A. Correct. Have you ever been personally 4 0. -- correct? involved in litigation? 5 A. No. Correct. 6 Do you know where Johnson & Johnson Have you ever had any disciplinary O. Q. sources its talc for those products? action initiated against you? 8 Again, I read this in passing in the A. No. 9 materials here. MR. HEGARTY: You want to go 10 Do you know what Johnson & Johnson's 10 ahead and take that break. 11 testing protocols are for testing talc? DR. THOMPSON: Sure. 12 12 I have read in the course of MR. HEGARTY: Take a break. 13 <sup>13</sup> preparing this report a lot regarding testing Let's go off the record. <sup>14</sup> protocols and history of testing protocols and the 14 (Whereupon, at 12:03 p.m., a <sup>15</sup> different methods and the different thresholds for 15 luncheon recess was taken.) 16 <sup>16</sup> detection, for sensitivities, you know, going --17 going back to the CIR J4-1 standard. 18 18 This has all been very interesting <sup>19</sup> to read and I've learned a lot about it, you know. 19 <sup>20</sup> So I -- I am glad to have that knowledge now and 20 <sup>21</sup> to use that as part of, you know, the material 21 22 <sup>22</sup> I've considered -- I've considered for these 23 <sup>23</sup> opinions. 24 24 Before -- before becoming involved Page 211 Page 213 <sup>1</sup> in this case, no, I had no knowledge about how AFTERNOON SESSION <sup>2</sup> Johnson & Johnson tested for asbestos. (12:52 p.m.) 3 And do you still -- do you currently WILLIAM M. SAGE, MD, JD <sup>4</sup> today, as of today, do you know the protocols that called for continued examination and, having been <sup>5</sup> Johnson & Johnson uses in testing its baby powder previously duly sworn, was examined and testified <sup>6</sup> for the presence of asbestos? further as follows: 7 Again, I've seen references to these EXAMINATION (CONTINUED). 8 <sup>8</sup> that were interesting to read. I couldn't --MR. HEGARTY: We're back on 9 couldn't tell you. the record. 10 With regard to ovarian cancer, are (Document marked for 11 you able to cite for me the subtypes besides identification as Sage Exhibit 10.) 12 serous? 12 BY MR. HEGARTY: 13 13 Again, no. I would look them up. Dr. Sage, over the break there was a copy made of your current curriculum vitae, which <sup>14</sup> That would be true for most cancers. 15 I marked as Exhibit No. 10. Do you know what the incidence rate 16 <sup>16</sup> is of ovarian cancer in this country? Would you tell me if Exhibit No. 10 I would only be guessing. Again, 17 is a copy of your current curriculum vitae? <sup>18</sup> this is sort of a fundamental aspect of expertise 18 I will look to see if it has the <sup>19</sup> is you don't really memorize a lot of things. You current visiting positions on it. <sup>20</sup> look things up. Well, now we have the problem that 21 Have you ever spoken at a seminar at 21 it only has the odd numbered pages in it. 22 <sup>22</sup> the request of a plaintiff's lawyer? MS. PARFITT: Oh, great. 23 Hmm. I've spoken at many Well, that was --<sup>24</sup> conferences at the request of defense lawyers. I 24 MR. HEGARTY: All right.

Page 216 1 Well, we'll -- we'll go ahead and replace <sup>1</sup> a copy in front of you. 2 So do you have your report in front it at a break. 3 THE WITNESS: That could be a <sup>3</sup> of you? 4 A. I do. yes. <sup>5</sup> BY MR. HEGARTY: 5 O. If we look at paragraph 10 of your report, you say in the middle of the paragraph as Q. Okay. 7 Would it help you to work with the <sup>7</sup> far as what you -- your research included and what one I have? your review included were "relevant corporate documents requested of counsel." No. We'll go ahead. We need to O. <sup>10</sup> mark it for the -- for the record. The next break 10 Do you see that phrase? 11 we'll get to it. Yes. A. 12 12 Now, you mentioned the notice of Q. Are you saying that you specifically <sup>13</sup> asked for certain documents that were requested of deposition. 14 counsel for plaintiff? Do you have a copy of that? 15 15 I'm saying that apart from Facts Α. I do. 16 What is the exhibit sticker on <sup>16</sup> About Talc and other easily accessible corporate O. 17 there? documents from public websites, I didn't have 18 access to corporate documents from the litigation The exhibit sticker is 6. Α. 19 that were relevant to the report; and I asked for O. 20 as many of those as was feasible to be produced to You said you now had a chance to <sup>21</sup> me. read the 18 paragraphs in that exhibit? 22 22 I have. And as best as you can, can you 23 Did you provide to your counsel for <sup>23</sup> reconstruct for me the language you were -- you Q. <sup>24</sup> purposes of that notice all the materials that you <sup>24</sup> would have -- that you used in making that Page 215 Page 217 <sup>1</sup> have that are described in those paragraphs? 1 request? 2 Yes, absolutely. I would have asked for -- sure, I 3 DR. THOMPSON: And --<sup>3</sup> can tell you. Let me categorize that for you. 4 THE WITNESS: I had -- I had So category 1, as I've said 5 repeatedly, was making sure I had both sides of gone through this orally. I just had not 6 seen the document before. <sup>6</sup> the litigation story. So if I had been receiving, 7 MR. HEGARTY: And Dr. Thompson <sup>7</sup> say, scientific studies that were generally 8 had something to say. supportive of the plaintiffs' case, I wanted to 9 DR. THOMPSON: And just for <sup>9</sup> know what was generally supportive of the 10 <sup>10</sup> defendants' case, etc., etc., and the big picture the record, we filed objections to the 11 of the litigation. production request. 12 12 MR. HEGARTY: And you've --Point 2 would be information related 13 this is directed to Dr. Thompson. 13 to Johnson & Johnson's regulatory compliance, or 14 attitudes towards regulatory compliance, or You produced the documents 15 that you considered were not contacts between the sort of drug side of the 16 objectionable to the deposition notice? business in a regulatory sense and the people who 17 were responsible for decisions regarding DR. THOMPSON: Correct. BY MR. HEGARTY: cosmetics. 19 19 Doctor, I want to talk in more And point 3 would have been because 20 detail about your expert witness report. so much of my report is about the informational 21 <sup>21</sup> environment and informational obligations, you So I'm going to start walking <sup>22</sup> through the paragraphs. So you might want to have <sup>22</sup> know, the sort of marketing strategy, branding <sup>23</sup> that available. That's previously been marked as <sup>23</sup> strategies, changes in that, those sorts of

<sup>24</sup> Exhibit No. 4. Although I know you have your own

<sup>24</sup> things. Some of which were provided to me in the

<sup>1</sup> form of deposition transcripts. Some of which may <sup>2</sup> have been, you know, exhibits to depositions. I

<sup>3</sup> didn't track them in a formal way.

As you mentioned earlier, though,

<sup>5</sup> you don't know the methods by which the attorneys

<sup>6</sup> for the plaintiffs went about selecting documents

<sup>7</sup> in response to those requests, correct?

A. Correct.

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9 And you indicated previously that Q.

<sup>10</sup> you have not done any type of quality control

<sup>11</sup> analysis yourself as to whether you did get all

12 the documents that you were thinking you would get

pursuant to these requests, correct?

DR. THOMPSON: Object to form.

THE WITNESS: I felt I had the quality control analysis I needed to do, which really had to do with issues that appeared to be incompletely handled or issues that seemed to be not

documented at all.

21 I didn't feel like I was, you 22 know, looking for some type of smoking 23 gun documents. Not the type of report

24 that I'm producing.

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<sup>1</sup> BY MR. HEGARTY:

Did you do any sort of formal task

<sup>3</sup> where you intentionally looked for documents

<sup>4</sup> yourself that thought you should have to see

<sup>5</sup> whether you did get those?

Do you follow my question where you <sup>7</sup> did some sort of quantitative or qualitative

<sup>8</sup> analysis of the documents you were -- you received

<sup>9</sup> to make sure that the methods used captured what

you were expecting to get?

I follow your question.

12 I actually found that the deposition

13 transcripts were in some ways a good guide to the

<sup>14</sup> full scope of available information. I didn't try

15 to document them. I sort of made a practice of <sup>16</sup> not doing marks and highlights and notes on

<sup>17</sup> things. It didn't seem practical to do so as

<sup>18</sup> opposed to just drafting the report as, you know,

19 in sections and leaving areas of it for further

<sup>20</sup> development.

But I was -- I was quite

<sup>22</sup> comfortable. This was, again, you know, this

23 skill of litigation is unfamiliar to me, and I was

<sup>24</sup> working as best I could; but I felt like at the

<sup>1</sup> end of the day I had everything I needed.

In terms of the materials you do

<sup>3</sup> have in front of you today, did you put any notes

or make any markings on any of them?

In preparation for the deposition,

yes. In preparation of the report, no.

I'm talking about specifically on

materials you have in front of you.

Did you put any handwritten notes

into them?

15

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A. What I'm saying is -- so my own

report, in preparation for talking to you today,

as you can see I have, you know, underlined things

as reminders to myself --

Q. Okay.

16 -- in particular areas. I have not

annotated any of the other materials.

We're on, I think, Exhibit No. 11.

We'll designate for purposes of the deposition as

Exhibit No. 11 the notebook we have in front of

you. So we'll -- why don't we go ahead and make a

copy of that after the deposition, okay?

24 (Notebook marked for

Page 221

Page 220

identification as Sage Exhibit 11.)

BY MR. HEGARTY:

And that would include any mark --

<sup>4</sup> the copies of any -- the copy of your report that

has some markings of yours on it, right?

A. Yeah.

Okay. I want to next look at

paragraph 11 of your report. You say in paragraph

11 or paragraph 11 you reference -- you make a

reference to highly profitable cosmetic -- "a

highly profitable cosmetic industry."

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Can you cite for me any information 13 you have on the profits of companies making

cosmetics over the 80 years you talk about in

paragraph 11?

16 So -- so if -- if I may just in

terms of how I organized the report because it

would facilitate the conversation.

19 The bolded unnumbered statements in

the discussion are how I organized the key points

<sup>21</sup> of the report. Those are the major categories,

<sup>22</sup> major insights, major conclusions and opinions. I

<sup>23</sup> just used the paragraph numbering sort of for

<sup>24</sup> convenience for the elaboration of those major

Page 222 Page 224 <sup>1</sup> points. <sup>1</sup> published in a 1995 article by Carr. 2 2 Do you recall that? I asked whether any particular <sup>3</sup> format was required by the court or by convention, 3 If you could refresh my --4 <sup>4</sup> and I was told no. So this was the approach that 0. <sup>5</sup> I -- that I adopted. Just so in case if you 5 -- recollection on that one. Α 6 <sup>6</sup> wanted to talk about the major points, they'll be MR. HEGARTY: I'm going to <sup>7</sup> in bold but not in numbered paragraphs. 7 show you what I've marked as Exhibit 8 With respect to profitability and No. 12. 9 <sup>9</sup> change in the industry, this statement was a (Document marked for <sup>10</sup> general statement consistent with statements that 10 identification as Sage Exhibit 12.) <sup>11</sup> were made in sort of the FDA's own documents over BY MR. HEGARTY: 12 the last couple of years talking about the need 12 This is a 1995 article author C. 13 for a more structured approach to cosmetic 13 Jeffrey Carr in the Journal of Regulatory 14 Toxicology and Pharmacology that summarizes a 1994 <sup>14</sup> regulation. 15 So ultimately the reason I ask that Workshop attended by FDA personnel, industry Q. <sup>16</sup> question is there's no citation to authority at personnel, scientists, and academics. 17 the end of this paragraph. Do you recall reading this article? 18 So my question is: What authority It is referenced in your materials. 19 did you -- do you rely on for the statement --Yeah, that's what I was just going statements in paragraph 11? to take a look to see where -- where it is 21 21 DR. THOMPSON: Object to form. referenced. 22 22 THE WITNESS: Again, I will It is referenced. 23 23 reiterate that there is no standard So my question --24 24 Yes. I recall -citation protocol that I'm aware of for Page 225 Page 223 this type of report. -- do you recall reading this? O. 2 2 This is a statement that Yes, I recall seeing this. A. 3 3 synthesizes things that I have read from And that article reported on a O. 4 the FDA and from other commentators. All <sup>4</sup> two-day meeting that looked at the safety of talc 5 in 1994, correct? of which has been produced to you as 6 material to be considered. 6 A. Correct. <sup>7</sup> BY MR. HEGARTY: You were not at this meeting, right? O. In making that statement, you did 8 A. 9 <sup>9</sup> not look at any specific profitability statements If you look at page 213 of this O. <sup>10</sup> by any company, correct? 10 article. 11 11 A. Correct. Α. Yes. 12 12 Q. Turning next to paragraph 13, you Q. On the -- in the right-hand column, first full paragraph beginning with the word --13 refer to a list of 100, as you call, dangerous --<sup>14</sup> as is quoted "dangerous, deceptive, or worthless the name "Dr. Gilbertson." 15 products." 15 Do you see that paragraph? 16 16 Talc was not on that list of hundred A. 17 17 products, correct? Q. The last line of that paragraph 18 18 I don't believe it was. This is a says: 19 <sup>19</sup> historical reference, and I certainly wouldn't be "In their joint evaluation, talc was stating that talc was. I don't know why it would proven to be among the safest of all consumer <sup>21</sup> have been. products." 22 You have referenced in your report Do you see where I'm reading? <sup>23</sup> and you made reference earlier to an FDA Workshop I do. That language jumps out at me <sup>24</sup> in 1994 that ultimately whose results were <sup>24</sup> as -- as language that is often included in

Page 226 Page 228 1 <sup>1</sup> Johnson & Johnson's marketing materials. interesting for its value as scientific 2 But do you dispute that as of the truth. <sup>3</sup> time of this meeting, 1994, that talc has proven 3 I tend to look at all of this 4 <sup>4</sup> to be among the safest of all consumer products? type of material in any regulatory 5 DR. THOMPSON: Objection. context as telling a story. It's usually 6 6 Form. a very rich story about how regulators or 7 7 potential regulators and regulated THE WITNESS: I have no 8 8 industries interact, including in such particular reason to credit or doubt this 9 9 particular statement in this particular workshops. 10 10 journal at this time. So it is interesting and 11 11 relevant, but it is not going to be a It -- as a statement, it 12 12 carries no particular authority for me, major aspect of my conclusion or reliance 13 13 regarding the safety of talc. but I have no basis for doubting the 14 14 BY MR. HEGARTY: sincerity of the people who wrote it. 15 15 BY MR. HEGARTY: If you would next turn over to page 16 You agree that this article is <sup>16</sup> 215 and look at the last line in the left-hand 17 relevant to the analysis -- your analysis in your column carried over to the top of the right-hand 18 report, correct? column. In particular, the sentence reads: 19 19 "Following the many issues raised by DR. THOMPSON: Objection. 20 all presenters, the ensuing discussion generally Form. 21 agreed that, while some weak association between THE WITNESS: I would -- I 22 talc and ovarian tumors has been reported, it was would agree in -- I would agree -- well, 23 not sufficient warning for concern." let me -- let me go back and begin that 24 Do you see where I'm reading? answer again. Page 229 Page 227 1 I would reiterate that I'm not A. I do. 2 offering an opinion as to causation. If O. Again, that is a statement that's 3 you are pointing to this as, at the time, <sup>3</sup> relevant to the safety of talc as of the time of 4 a casual synthesis of international this workshop, correct? 5 DR. THOMPSON: Object to form. standards with respect to the regulation 6 of talc in consumer products, I would 6 THE WITNESS: Not 7 say, yes, it's relevant. necessarily. It's -- it's a summary of 8 8 BY MR. HEGARTY: attendees' impressions of a particular 9 9 You do -- you do address in your workshop conversation. It carries the 10 report within the context of your focus safety of way that one would give that, which is 11 talcum powder, correct? that at least in the opinion of the 12 12 A. Yes. person writing this summary I don't 13 13 know -- and we could, I guess, look up, The statement I just read concerns 14 14 the safety of talcum powder, correct? you know -- the discussion was generally 15 15 DR. THOMPSON: Objection. -- generally not -- the discussions were 16 16 generally unconcerned about talc safety Form. 17 17 THE WITNESS: Yes. It is in at the time, but it's the discussions at 18 18 an executive summary. It carries exactly a conference. 19

the weight that an executive summary of a conference proceeding carries for me in quantum Q. You said the

Q. You said the discussions were
 generally unconcerned, or what did you say? I
 didn't hear you.

<sup>23</sup> A. Yes. I was actually giving you the <sup>24</sup> answer that I suspect you wanted in that instance

particular document than it is

all my work, which is, it is relevant.

It is interesting. It may be more

interesting for its presence in this

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Page 230 Page 232 <sup>1</sup> is, yes, for the -- as reported by this observer <sup>1</sup> dispute that as of the time this publication was <sup>2</sup> and published in this unreviewed executive summary <sup>2</sup> made, 1995, concerning a meeting in 1994, that <sup>3</sup> of one conference that I'm sure was, you know, <sup>3</sup> these were proper conclusions to draw from the <sup>4</sup> convened with -- with decent scientific <sup>4</sup> evidence, the two conclusions we read from this <sup>5</sup> intentions, the discussions appeared to not be paper? 6 <sup>6</sup> terribly concerned about toxicity. DR. THOMPSON: Objection. 7 You say "unreviewed." Form. 8 You understand this is peer-reviewed THE WITNESS: These 9 publication, right? conclusions strike me as telling an 10 A. Executive --10 incomplete story, and I wouldn't attach 11 DR. THOMPSON: Objection. 11 any particular scientific weight to 12 12 THE WITNESS: -- summary -those, again, in the way that I would 13 13 DR. THOMPSON: Whoa. sort of read a regulatory history and 14 14 make sort of expert judgments about a Objection. 15 15 THE WITNESS: In my regulatory process. 16 16 experience, executive summaries of I would say that as far as 17 17 conference proceedings are not this particular conference goes, it 18 18 peer-reviewed. appears that the discussion did not 19 BY MR. HEGARTY: 19 result in inducing a sudden regulatory 20 20 change. This was a conference, as I --Do you know with regard to this <sup>21</sup> document specifically whether it was 21 as I recall, jointly sponsored by the FDA 22 peer-reviewed? by industry and by an International 23 23 I do not know, but it would be my Society of Regulatory Toxicology and <sup>24</sup> professional view that anybody reading this 24 Pharmacology, which I'm afraid I don't Page 231 Page 233 <sup>1</sup> summary would not expect it to have been reviewed. know anything about. 2 Are you aware that there's a And, you know, in terms of 3

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whether this particular topic -- whether this particular topic, you know, promoted, you know, sort of prompted action that would dislodge the then prevalent regulatory standards, it appears not.

But that's more what I would read this for. I don't -- I don't read this document as, you know, authoritative science. It's a conference proceeding.

#### 13 BY MR. HEGARTY:

14 Let's look at paragraph 15 of your O. 15 report.

16 In that paragraph, you say a central aspect of the federal cosmetics regulations are "reliance on manufacturer and industry 19 self-regulation."

20 Where in the regulations for cosmetics is the phrase "self-regulation"?

22 It is clear from FDA's website. It <sup>23</sup> is clear from every major address that has been <sup>24</sup> given either by the agency or, for that matter, by

<sup>3</sup> transcript of the two-day proceedings?

A. I hope so, yes. I am not aware of <sup>5</sup> that but...

Did you make a request for such a Q. <sup>7</sup> transcript?

8 A.

Q. You don't cite to this -- this

<sup>10</sup> article substantively in your expert report,

correct?

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A. Correct.

13 Okay. From your analysis in this

case, do you dispute that as of the time of this

<sup>15</sup> conference the statements that we looked at on

these two different pages?

17 DR. THOMPSON: Object to form.

18 THE WITNESS: I don't think I 19 understood that question.

20 BY MR. HEGARTY:

> Q. Sure.

22 In your analysis of what you did for purposes of this case, do you dispute -- or from

<sup>24</sup> your analysis that you did in this case, do you

Page 236 <sup>1</sup> representatives of the cosmetic industry that the A. Yes. <sup>2</sup> principal form of governance of cosmetics is 2 O. FDA may seek a seizure of cosmetics <sup>3</sup> self-governance assigned to industry often in some not in compliance with the law, correct? <sup>4</sup> fairly -- I should say the manufacturers and Α. Yes. <sup>5</sup> sellers -- often in very specific ways. 5 Q. FDA may initiate criminal action But, no, the word "self-regulation" against a person violating the law, correct? <sup>7</sup> doesn't appear in the statute or the regulation. A. Through the Department of Justice, 8 <sup>8</sup> It does, interestingly, appear in the remarks and yes. <sup>9</sup> the characterization of the regulatory process Q. FDA can also issue a warning letter 10 from both the, you know, from the FDA and from the if they think a product is adulterated or <sup>11</sup> CFTA or successor organizations. misbranded, correct? 12 12 This does not seem to be something Α. Yes. 13 <sup>13</sup> that is seriously contested by any party. O. FDA can also request that the 14 You also state that FDA "lacks manufacturer recall a product, right? 15 routine authority to assure the safety of cosmetic The recall, a voluntary recall, products or ingredients." indeed, the FDA can request it. I could request 17 That's not true, is it? it just as much. 18 18 DR. THOMPSON: Object to form. O. If FDA asks for a recall of the 19 THE WITNESS: That is true. product, most manufacturers comply with that 20 request, correct? They do -- they do not have routine 21 21 authority. There are foundational A. Correct. 22 22 pillars of food, drug, and cosmetic DR. THOMPSON: Objection. 23 regulation in terms of adulteration and BY MR. HEGARTY: 24 misbranding. There are some subsidiary Q. FDA can also issue something called Page 237 Page 235 <sup>1</sup> a guidance document, right? authorities. 2 But comparing FDA's drug A. 3 regulatory regime to what it would have Q. And a guidance document is, like it 4 to do in order to make a significant <sup>4</sup> sounds, it sets forth FDA's thinking about a type 5 of product or an ingredient, correct? effort to -- to verify the safety of 6 cosmetics to prevent injuries, or even to Yes. The resources available to do <sup>7</sup> this in the cosmetics domain are a tiny fraction address injuries that would occur, is not 8 what I would call routine authority. of the resource available to issue guidance documents in, say, drug or device domains. BY MR. HEGARTY: 10 10 Well, FDA can issue regulations that And guidance document, while not require there to be a warning on a cosmetic, having the force of regulation, but it does tell 12 correct? 12 the industry very clearly what it should do in 13 regard to an ingredient, including what the 13 A. Indeed. 14 contents of a warning should be, correct? If FDA makes a determination that a cosmetic product is adulterated or misbranded FDA 15 Not necessarily. The -- the FDA 16 can take action, correct? <sup>16</sup> could issue a regulation that requires a warning. 17 A. Yes. That would go through an extensive procedure 18 Q. FDA can work through the Department regarding both issuance and evaluation and would 19 of Justice to remove adulterated or misbranded be subject to both formal and informal challenges. products from the market, correct? All of this -- all of these 21 A. Yes. 21 statements with which you've had me agree, some to <sup>22</sup> having residual authority to having some strong FDA may request a federal court to <sup>23</sup> issue a restraining order against the sale of a <sup>23</sup> pillars of obligation under the 1938 Act, which <sup>24</sup> cosmetic, correct? <sup>24</sup> really I will, you know, convey as my expert

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<sup>1</sup> opinion are essentially informational obligations.

- <sup>2</sup> And there is a lot really -- and they really fall
- <sup>3</sup> exclusively on the manufacturers with very
- <sup>4</sup> little -- with very little advanced safeguards,
- <sup>5</sup> with very little continuing oversight, and with
- <sup>6</sup> almost no self-executing recourse.

I would characterize the sort of post-1938 cosmetic regime as very similar to the pre-1938 drug regime.

- 10 Are you aware of situations where <sup>11</sup> FDA has issued a guidance document regarding warnings as it relates to a cosmetic?
- 13 I believe I have seen those. None <sup>14</sup> is immediately springing to mind, but, yes.
- 15 In particular, do you recall FDA <sup>16</sup> issuing a guidance document regarding certain warnings that should be used on a product called alpha hydroxy acids? Do you recall seeing it?
- 19 I recall seeing it. I don't recall 20 the details right now.
- 21 But using a guidance document in <sup>22</sup> this sense is FDA's way of telling an industry <sup>23</sup> that a warning should be put on a label without <sup>24</sup> going through the entire process of issuing a

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And I think this is something that both FDA and the industry

- acknowledge and each of them alters their
- 4 feelings about it from time to time based
  - on familiar and predictable factors, and
- 6 that's one reason we have another major
  - bill in Congress at the moment.

#### BY MR. HEGARTY:

- The FDA has not issued any guidance document with regard to talcum powder products, correct?
- 12 I have not seen any -- any final <sup>13</sup> guidance documents. You've shown me, you know, <sup>14</sup> responses to Citizen's Petitions. I have shown <sup>15</sup> you internal -- internal evaluations from the <sup>16</sup> 1990s.
- 17 Q. And you would expect that FDA knows <sup>18</sup> about lawsuits brought over the use of talcum powder products, correct? 20
  - A. Of course.
- 21 Q. And FDA knows about allegations of <sup>22</sup> finding asbestos in talc, right?

23 DR. THOMPSON: Object to form. 24 THE WITNESS: Yes.

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<sup>1</sup> regulation, correct?

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DR. THOMPSON: Object to form. THE WITNESS: If I may -- if

I may make an analogy.

The Federal Trade Commission engages in competition advocacy all the time where it sends letters to state legislatures and to state regulators and to other parties suggesting that something they're doing is anticompetitive, attempting to influence them without the extreme measure of filing an administrative action or a federal lawsuit for a preliminary injunction.

I do not think that FDA's authority over cosmetics is that much greater than FTC's authority over potentially anticompetitive, you know, state laws and practices.

Yes, it carries a lot of weight. It will be taken seriously. Sometimes it will be acted on, but the whole point is, it's not self-executing.

# <sup>1</sup> BY MR. HEGARTY:

- FDA knows about epidemiology? O.
- 3 FDA has found -- let me supplement. A. <sup>4</sup> I'm sorry to interrupt.

FDA has found asbestos in talc and <sup>6</sup> has requested voluntary recalls that have been complied with by your client and others.

And we'll get to that.

9 FDA knows about epidemiologic studies and toxicology studies involving talc and ovarian cancer, correct?

> DR. THOMPSON: Object to form. THE WITNESS: Yes. I mean, this -- we are kind of anthropormophasizing FDA a little bit here. I mean, we are -- FDA's cosmetic oversight function is an office within a Center that also deals with food safety.

And in terms of rising to the level where FDA will expend resources given its relatively limited and -- and tentative regulatory authorities, you know, I don't really know how to say what FDA knows.

Page 244 1 FDA may know a lot of things <sup>1</sup> correct? 2 2 in that it's on notice, but there may be A. Exact ---3 3 many obstacles to FDA action. DR. THOMPSON: Objection. 4 <sup>4</sup> BY MR. HEGARTY: Form. 5 FDA has never issued a regulation THE WITNESS: I exactly 6 <sup>6</sup> requiring that talcum powder products contain a agree, but that is my point. These are <sup>7</sup> warning about the risk of ovarian cancer, correct? 7 the two pillars of FDA authority. 8 A. Correct. Because there is so little other 9 authority conferred on FDA on the Q. FDA has never declared talc-based 10 <sup>10</sup> slide patterns to be adulterated or misbranded, cosmetic side of the FDCA and such that, correct? 11 indeed, if FDA is committed to reaching a 12 12 MS. PARFITT: Objection. result in case of something like asbestos 13 13 being found in talcum-based baby powder, Form. 14 14 yes, it will make those findings because THE WITNESS: Correct. 15 15 BY MR. HEGARTY: that's how it goes to court and get the 16 16 results it seeks. O. FDA has never --17 17 BY MR. HEGARTY: I should -- may I correct that 18 18 statement? You're aware that FDA has never 19 declared Johnson & Johnson talcum powder product Q. Sure. 20 as being adulterated or misbranded? So in connection with finding <sup>21</sup> asbestos in talcum powder products, FDA has 21 DR. THOMPSON: Objection. <sup>22</sup> stated, if not formalized, a conclusion that those BY MR. HEGARTY: 23 products are adulterated. You know that, right? 24 24 Well, there's a particular DR. THOMPSON: Object to form. Q. Page 245 <sup>1</sup> formalized finding or statement that FDA makes if THE WITNESS: Again, I would 2 <sup>2</sup> it finds a product adulterated or misbranded, like to know what the statements were 3 <sup>3</sup> correct? made in 2019. I've read this, without --4 It makes such statements in without reviewing those materials. 5 <sup>5</sup> anticipation of a judicial procedure that would Because I know that there were statements <sup>6</sup> result in the outcome it wants. If it can obtain 6 made that asbestos by the FDA or by FDA 7 <sup>7</sup> that outcome less formally, it will not go to senior officials that asbestos in talcum 8 <sup>8</sup> those lengths. powder would be an adulterant. 9 Did they -- did the FDA make a FDA has never made the statement 10 formal declaration? I don't believe they <sup>10</sup> that any talcum powder product manufactured by 11 Johnson & Johnson is adulterated or misbranded --12 DR. THOMPSON: Objection. 12 BY MR. HEGARTY: 13 13 Form. Has FDA ever issued a guidance document suggesting that products containing talc <sup>14</sup> BY MR. HEGARTY: 15 have a warning on them regarding ovarian cancer? Q. -- correct? Not to my knowledge. I'm not sure of that insofar as the <sup>17</sup> 2019 voluntary recall was -- was made with a clear If you look at paragraph 17 of your <sup>18</sup> signal from the FDA that an unrecalled product report, you say in paragraph 17 that "FDA itself <sup>19</sup> would be considered adulterated and further steps <sup>19</sup> recognizes its limitations in effectively <sup>20</sup> would be taken. That was certainly my -- my regulating cosmetics." 21 <sup>21</sup> reading of what -- of the documents that I saw. And those are your words, not FDA's <sup>22</sup> words, correct? You know that the terms <sup>23</sup> "adulterated" and "misbranded" are terms of art In paragraph 18, all of the quoted

<sup>24</sup> that FDA must use in order to take further action,

<sup>24</sup> testimony, which is what continues to paragraph 17

Page 246 Page 248 <sup>1</sup> thoughts, are FDA's words. (Document marked for My question is specifically as it identification as Sage Exhibit 13.) <sup>3</sup> relates to 17. <sup>3</sup> BY MR. HEGARTY: You cannot cite for me anyone from And the first statement I want to go <sup>5</sup> FDA stating that it has limitations -- using the to that you left out of your report is over on <sup>6</sup> words you use "limitations effectively regulating page 1 at the bottom, and in particular, <sup>7</sup> cosmetics"? <sup>7</sup> Ms. Mayne's testimony in this document that you A. Both the Susan -- the Susan Mayne did not cite says: <sup>9</sup> testimony here, various statements from my "We believe that most cosmetics on <sup>10</sup> acquaintance, Scott Gottlieb, as commissioner have the market of the United States are indeed safe, <sup>11</sup> all been, you know, in -- consistent with that and in our experience, most firms are responsible 12 statement. <sup>12</sup> actors - they care about consumer safety and the 13 Well, let's talk about what you say <sup>13</sup> reputation of their brands, and in those rare <sup>14</sup> in paragraph 18 where you purport to provide cases when safety issues do arise, many firms work <sup>15</sup> relevant selected excerpts of the testimony of <sup>15</sup> with us cooperatively to address them." 16 <sup>16</sup> Susan Mayne, and I disagree that you did that and You didn't include that statement, <sup>17</sup> I'll show you why I disagree that you did that. <sup>17</sup> did you? 18 18 And let me ask you first. I completely -- I think that is a 19 Is it your methodology -- was it 19 very well-crafted statement. I saw no reason to your methodology in your report to just cite include that in this part of my report. <sup>21</sup> portions of a document that help your subjective 21 The next statement you didn't <sup>22</sup> include is the one that is right after that: <sup>22</sup> review, your subjective view and not give the <sup>23</sup> reader an objective summary? "We also understand that most 24 DR. THOMPSON: Objection. <sup>24</sup> ingredients used in cosmetic products have been Page 249 Page 247 <sup>1</sup> used in cosmetics for many decades, and we are not Form. 2 <sup>2</sup> aware of safety concerns regarding most THE WITNESS: The answer to 3 3 ingredients." that accusation is, of course not. The 4 4 elaborate -- the elaboration is that my You didn't include that statement? 5 point is the FDA recognizes its I did not. 6 6 O. If you look over to page 4 at the limitations. 7 <sup>7</sup> bottom of that page, second to last paragraph. I would also comment that no 8 "FDA evaluates concerns about head of an agency stands up and gives a 9 blanket condemnation of her or his own <sup>9</sup> ingredients or products based on currently 10 <sup>10</sup> available science and data, much of which is work. It's simply not done. publicly available as FDA does not have authority 11 BY MR. HEGARTY: 12 12 to require companies to provide it with safety, Well, there are portions of Q. <sup>13</sup> Ms. Mayne's testimony that are relevant that you compositional and other relevant information about didn't tell the reader, aren't there? cosmetics. FDA also supports and conducts 15 <sup>15</sup> research related to cosmetics safety to support MS. PARFITT: Objection. 16 <sup>16</sup> our regulatory activities, as allowed by our Form. 17 resources. What we have safety concerns about DR. THOMPSON: Objection. 18 18 ingredients we will act swiftly to inform and Form. 19 <sup>19</sup> advise consumers of any identified public health THE WITNESS: If you would 2.0 like to show me something, which I think 20 risks." 21 21 you would. You did not include that statement 22 <sup>22</sup> in your report, did you? MR. HEGARTY: I'll show you. 23 I did not. Though I do not think I marked next as Exhibit No. 13 the 24 <sup>24</sup> anything you read is inconsistent with my statement you cited from Susan Mayne.

Page 65 of 110 Page 252 1 <sup>1</sup> statement in paragraph 17 regarding limitations THE WITNESS: Yes. Yes, its 2 <sup>2</sup> and effectively regulated cosmetics. 2019 recall of talcum powder -- talcum 3 And in the last line of that powder products containing asbestos. paragraph -- I'm sorry -- page 4 says that: <sup>4</sup> BY MR. HEGARTY: "Ensuring the safety of cosmetics is Q. Besides that 2019 statement? 6 <sup>6</sup> a high priority for us." Direct -- directly consumer -- to You didn't include that statement, consumers, not to my knowledge. 8 So you in your previous answer did you? 9 indicated that there's somehow -- that this I did not. A. 10 statement should somehow be taken with a grain of Q. FDA has never identified any health -- any public health risks with talcum powder salt because she's a political appointee. 12 12 products. True? Is that what you're saying? 13 13 DR. THOMPSON: Object to form. DR. THOMPSON: Objection to 14 14 THE WITNESS: No, I'm sorry. form. 15 15 THE WITNESS: Again, if we go I was thinking out loud. 16 16 to that internal guidance document, there I concluded -- again, this is 17 17 is concerning language there. And if we verifiable. I know that Susan Mayne 18 18 go to the 2014 Citizen's Petition retains the director -- directorship of 19 19 the Center at present. I said I do not response that we discussed earlier today, 20 20 know whether she's a political appointee there's concerning language there. 21 21 So indeed FDA has expressed or a career official. Could be either. 22 22 its -- its doubts regarding safety. No, that does not matter to my 23 BY MR. HEGARTY: 23 answer. 24 <sup>24</sup> BY MR. HEGARTY: Q. Well, FDA says in this document that Page 253 Page 251 <sup>1</sup> I just read that it will "act swiftly to inform You just admitted that and FDA found <sup>2</sup> and advise consumers of any identified public a public health risk through the finding -- its 3 health risk," right? <sup>3</sup> finding of asbestos -- in what it believes was And it has not done so with regard <sup>4</sup> finding of asbestos in a talcum powder bottle, it <sup>5</sup> to talcum powder products. True? took action, correct? With respect, this is a speech that 6 DR. THOMPSON: Object to form. 7 <sup>7</sup> a senior -- I'm not sure -- I would imagine -- I THE WITNESS: I think -- I <sup>8</sup> don't know if she's a career political appointee. 8 think we're -- we're diving down into the 9 <sup>9</sup> I would imagine she's career, but a senior weeds when the essence of the opinions I 10 10 official director of -- of an FDA Center is making offer, you know, really -- really have to <sup>11</sup> in Congressional testimony. This statement is 11 do with -- with the big picture. 12 <sup>12</sup> crafted to serve that role very effectively. Everything that I have seen 13

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I have no basis in giving my expert <sup>14</sup> opinions on Johnson & Johnson's lack of compliance <sup>15</sup> with the its regulatory and self-regulatory <sup>16</sup> obligations regarding why particular lines are in this statement. It strikes me as eminently <sup>18</sup> suitable and professional and appropriate for its 19 moment. 20 Well, has FDA done anything to <sup>21</sup> inform and advise consumers of any public health risks with talcum powder products?

and read from a number of sources, including sources from industry over a large number of years, identifies cosmetics regulation as having very limited statute -- statutory authority, having very few directly self-executing regulations, having very little FDA supervisory oversight, and placing the vast majority of the burden, really the exclusive burden, on manufacturers and sellers.

Such that I reject your

DR. THOMPSON: Objection.

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Form.

Page 256 1 suggestions that FDA taking occasional statements are not the relevant support 2 2 action shows that they will take all for the statement in paragraph 17. 3 necessary action or that them refraining <sup>3</sup> BY MR. HEGARTY: 4 from action means that there are no Let's look paragraph 19. 5 5 What is your reliance materials for problems. 6 the statements that you make in that paragraph? That said, I am happy to 7 support the notion that most consumer Most of the reliance materials come 8 products that are sold in America are from the collection of important, well-edited, 9 well-selected historical materials on cosmetics sold by reputable companies trying to do 10 the best they can and turn out to be regulation that are in the Hutt, Merrill, and 11 <sup>11</sup> Grossman legal casebook, which is the leading safe. I certainly hope and expect that 12 to be the case. casebook, you know. And I did some, you know, 13 BY MR. HEGARTY: subsequent, as we've discussed, you know, <sup>14</sup> exploration of some of the things that are cited. Let me go back to sort of where we <sup>15</sup> started. Some of the controversies that are described. 16 16 You purported to say that you cited Others come from statements that relevant excerpts of the testimony of Susan Mayne have been made in the Congressional hearings that as it relates to any limitations on FDA's ability are also cited more recently, but that postdate 19 to regulate the industry, but you didn't cite the the last edition of that casebook. portion of the statement that we just read that And it's been -- as a -- as an <sup>21</sup> says, if FDA has safety concerns, it will act. <sup>21</sup> expert in regulatory design and the regulatory Is it your testimony that that's not <sup>22</sup> process, I can say that the forces that have <sup>23</sup> induced the cosmetics industry at different times <sup>23</sup> relevant to the points you were making in this <sup>24</sup> part of your -- your report? <sup>24</sup> to take different positions on the extent of Page 255 Page 257 1 <sup>1</sup> federal government oversight are familiar and DR. THOMPSON: Objection. 2 <sup>2</sup> predictable, and I would be happy to enumerate Form. 3 THE WITNESS: I will defend <sup>3</sup> them for you. 4 not only the contents, but the structure You in your report, as it relates to 5 of what I wrote here. I have a paragraph this paragraph, cite from no one at Johnson & 6 that says the "FDA recognizes its Johnson commenting on federal safety regulations, 7 limitations" and then I have quotes that correct? 8 8 support the recognition of the DR. THOMPSON: Object to form. 9 9 limitations. THE WITNESS: I cannot 10 10 There might be another section recall. Though I did observe when I 11 11 of this or another report that talked looked at the companies that are 12 12 about the things that FDA does well or supportive of the current 13 13 right, but this is exactly what I think Feinstein-Collins legislation that 14 14 Johnson & Johnson is supportive of that it should be to support the statements I 15 15 made. legislation. <sup>16</sup> BY MR. HEGARTY: 16 BY MR. HEGARTY: 17 17 You read the statements and I read In looking at paragraph number 20, to you, and you intentionally chose to leave them you cite the statements by the PCPC president. 19 19 out of your report, correct? Do you know that he's not authorized 20 MS. PARFITT: Objection. 20 to speak for Johnson & Johnson, correct? 21 21 Α. Well, he's --Form. 22 22 DR. THOMPSON: Objection. DR. THOMPSON: Object to form. 23 23 THE WITNESS: I assume he's Form.

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THE WITNESS: Those

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the former president because this is

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historical material. If he's the current president, I was not aware of that.

Again, sort of following the way that I construct -- constructed this report, 19 is a general statement that is then documented in 20 and 21 and 22, showing changes of position.

But, yes, I would assume that the president of the industry trade association has never been authorized to speak for Johnson & Johnson.

#### 12 BY MR. HEGARTY:

13 And he talks about and makes <sup>14</sup> reference to "no unnecessary or burdensome regulation." That's what you cite in your -- in your paragraph.

17 Are you advocating in your report that there should be unnecessary or burdensome regulation on the cosmetic industry? 20

DR. THOMPSON: Objection.

21 Form.

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THE WITNESS: No. (Laugh).

<sup>23</sup> BY MR. HEGARTY:

Okay. So is it your testimony that Q.

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What is the current number of FDA
<sup>2</sup> personnel working in the Office of Cosmetics and
<sup>3</sup> Colors?
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A. I do not know.

O. What was -- what were the numbers of personnel working there between 2015 and 2020?

I do not know. It is still a small 8 office.

O. What is the current budget for this 10 office for 2021?

I have seen that number in passing. <sup>12</sup> But if we go -- go back to paragraph 18, the <sup>13</sup> direct quote from Susan Mayne, "our program for <sup>14</sup> cosmetics is approximately \$10 million," which is <sup>15</sup> about 3 percent of just that one Center's annual <sup>16</sup> budget of \$327 million. And, undoubtedly, if we <sup>17</sup> were going to compare this to the drug or device oversight budget, it would be a pittance. I would also note in that connection

<sup>20</sup> if we want to talk about budgets, which I'm more <sup>21</sup> than happy to do, that a major aspect of the <sup>22</sup> current Senate proposal is to institute user fees <sup>23</sup> on cosmetics companies, which is one way of <sup>24</sup> addressing the -- the budgetary challenges, very

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Page 260

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<sup>1</sup> it is wrong to not want unnecessary or burdensome
<sup>2</sup> regulation?
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3 DR. THOMPSON: Objection.

4 Form.

> THE WITNESS: I am citing his position expressed in 1995, which differs from the industry's position in 1998 described in paragraph 21, which differs from the 2012 position described in paragraph 22, and which almost certainly would differ from the position today as representing the industry's equivocations regarding a more aggressive federal regulatory role.

I would also note that the 1975 position regarding self-regulation is that we will do this or perhaps give the appearance of doing this in order to forestall regulations, which in 1995 Mr. Kavanaugh, on behalf of the industry, you know, in general opposed.

22 BY MR. HEGARTY:

23 In paragraph 21, you make reference <sup>24</sup> to statements made as it relates to 1998.

<sup>1</sup> similar to what happened in the prescription drug domain in the early 2000s.

In this part of your report, is it <sup>4</sup> your contention that FDA has not brought <sup>5</sup> regulatory action regarding talcum powder products <sup>6</sup> because its resources are limited?

A. Would you ask that again, please?

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9 Is it your contention as part of this part of your report that FDA has not brought regulatory action regarding talcum powder products because its resources are limited?

DR. THOMPSON: Objection.

Form.

THE WITNESS: My contention in this part of the report is to emphasize the twin responsibilities of information disclosure and manufacturer self-governance, substantiation of safety for products and for cosmetic products and ingredients.

In this particular part of this report, I'm not using this language to make a specific suggestion about

1 action or inaction regarding tale, but <sup>1</sup> on Johnson's Baby Powder and Shower to Shower that 2 indeed budgetary shortfalls causes <sup>2</sup> Johnson & Johnson has produced in this litigation, 3 relatively little action in any cosmetic <sup>3</sup> correct? 4 domain. A. Correct. 5 Q. We've also established that you're MR. HEGARTY: Do you mind if 6 not an expert on the testing procedures for talc, we take a quick break? 7 correct? DR. THOMPSON: Sure. 8 8 A. Correct. (Recess: 1:42 p.m. -9 Q. 1:51 p.m.) In particular, there's a test that 10 is conducted on talc called XRD. MR. HEGARTY: Okay. Let's go 11 Do you know what XRD is? X-ray back on the record. 12 BY MR. HEGARTY: 12 diffraction? 13 13 Okay. We are back on the record, If you take it away from the <sup>14</sup> Doctor, and next paragraph I want to look at is acronym, I understand what x-ray diffraction is. 15 You're not an expert in x-ray paragraph 26 of your report. 16 A. Certainly. 16 diffraction, correct? 17 17 Q. Actually, it's paragraph 27. A. No. 18 18 Q. You're not an expert in transmission A. Okay. 19 You make the statement at the end electron microscopy, correct? 0. that Johnson's Baby Powder -- "Johnson & Johnson's Again, I know the difference between <sup>21</sup> talcum powder products include other potentially <sup>21</sup> transmission and scanning electron microscopy; <sup>22</sup> hazardous substances in varying amounts." but, no, I'm not a transmission microscopist. What was your methodology for --You're not an expert in polarized <sup>24</sup> well, first of all, before I ask that. <sup>24</sup> light microscopy, correct? Page 263 Page 265 A. What potentially hazardous Correct. substances are you referring to in that paragraph? O. You're not an expert in scanning Again, just forgive me because I electron microscopy? <sup>4</sup> guess this should -- this should be evident, but, As I just said, no. <sup>5</sup> again, to go to the structure of the report, Q. And before being contacted by <sup>6</sup> there's a bolded statement about paragraph 27. counsel for plaintiffs in this case, you had never <sup>7</sup> Paragraph 27 basically introduces a series of <sup>7</sup> considered any of those testing procedures that we <sup>8</sup> paragraphs that provide the detail on paragraph just talked about, correct? 9 DR. THOMPSON: Object to form. 9 27. 10 10 So those were the categories of THE WITNESS: I had never 11 additional or incompletely specified or considered any of those testing 12 potentially hazardous or hazardous substances that 12 procedures for talc. I have seen those 13 <sup>13</sup> either are or may be contained in talcum powder testing procedures in use or read about 14 14 products. them in use in various contexts over the 15 And your methodology for making that 15 Q. decades. <sup>16</sup> conclusion was the review of the documents that we <sup>16</sup> BY MR. HEGARTY: talked about earlier in the deposition? 17 If we look at -- well, let me back <sup>18</sup> up. 18 Exactly. 19 19 DR. THOMPSON: A late object You had never prior to being 20 contacted by plaintiffs' counsel commented in any to form. 21 publication of yours or in any lecture or in any MR. HEGARTY: That's okay. 22 BY MR. HEGARTY: class of yours on XRD, TEM, PLM, or SEM, correct? And we've already established that 23 A. That is correct. <sup>24</sup> you have not analyzed all of the testing documents 24 Q. If we look at the next paragraph 28,

Page 268 <sup>1</sup> in that paragraph you refer to something called <sup>1</sup> consider asbestos, but geologically related in <sup>2</sup> "platy talc" (indicates). <sup>2</sup> terms of often being in the same deposits and at Do you know where that phrase is <sup>3</sup> least based on the IARC conclusions having similar <sup>4</sup> ever cited -- can you cite to me where that phrase <sup>4</sup> health hazards to asbestos. <sup>5</sup> is cited in any publication? You did not do a comprehensive DR. THOMPSON: Object to form. <sup>6</sup> analysis of the literature on talc fibers and 7 THE WITNESS: I can't -- I ovarian cancer risk, correct? 8 can't right now. I have seen DR. THOMPSON: Object to form. 9 9 descriptions of it in various of the THE WITNESS: I don't know 10 10 documents that I have reviewed. that anybody has done a lot of that 11 11 research because I think it's very hard The attempt here was not to be 12 12 exhaustive regarding terminology, but to do given that talc has not been 13 13 where there were a couple of phrases that systematically assayed for fibrous 14 14 seemed to be in common use for the same content. 15 15 substance, to put them in the same But I think my -- my belief 16 16 paragraph. would be -- I guess my opinion would be 17 17 BY MR. HEGARTY: that to the extent that fibers are an 18 18 inevitable component of a talc deposit, Do you consider yourself an expert <sup>19</sup> in IARC's processes and procedures for its review 19 that there can be some very significant 20 of substances? associations between talc fibers and 21 21 A. No. ovarian cancer. 22 22 BY MR. HEGARTY: O. You've never been involved in an <sup>23</sup> IARC proceeding, correct? You said that talc fibers are an 24 <sup>24</sup> inevitable component of talc. I think that's what A. Correct. Page 267 Page 269 You've never before this report <sup>1</sup> you said. <sup>2</sup> cited to an IARC Monograph in any document you A. That's my --<sup>3</sup> prepared, correct? O. What's your source -- what's your DR. THOMPSON: Object to form. source for that statement? 5 THE WITNESS: Not that I That's my understanding based on the 6 <sup>6</sup> documents. I, you know, can't say, you know, the recall. <sup>7</sup> BY MR. HEGARTY: prevalence fiber count, the assays for talc fibers. In fact, the assays for asbestos seem to You had not read the IARC monographs <sup>9</sup> for talc not containing asbestiform fibers and <sup>9</sup> be contested and in flux, and there seems to be a <sup>10</sup> asbestos prior to being contacted by counsel for consensus, at least within the FDA, that there plaintiffs, correct? needs to be some improvement to those standards. 12 12 A. You cite in this paragraph, that is That is correct. Next paragraph 29 begins by 13 paragraph 29, to IARC's 2012 monograph. <sup>14</sup> referring to something called "fibrous That 2012 monograph nowhere uses the 15 (asbestiform) talc." phrase "fibrous talc," does it? 16 16 What is your definition of "fibrous DR. THOMPSON: Object to form. 17 17 (asbestiform) talc"? THE WITNESS: I would -- I 18 18 So my understanding is that talc would have to review it. The -- the 19 <sup>19</sup> that doesn't have the flat morphology that makes monograph on talc not containing <sup>20</sup> it hydrophobic and generally, you know, useful in 20 asbestiform fibers -- hold on, figure out 21 <sup>21</sup> something like baby powder can exist in various where we are -- is an evaluation of the <sup>22</sup> fiber forms. And my review of the documents we 22 platy talc.

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<sup>23</sup> described refers to that as often "fibrous" or

<sup>24</sup> "asbestiform talc" distinct from what we would

I reviewed all of this to see

how they were cabining the questions they

Page 270 Page 272 1 were asked, and I made sort of note of <sup>1</sup> asbestiform fibers? 2 It's the asbestiform fibers in talc all of that for purposes of the report. 3 I am not giving either geology containing asbestiform fibers, to be precise. 4 opinions or opinions on causation, but I So you're defining for purposes of 5 noted the conclusions in the later IARC this paragraph talc containing asbestiform fibers 6 or -- I'm sorry. regarding asbestos that -- that its 7 conclusions regarding asbestos would You're defining in this paragraph 8 equally apply to -- to what we'll call asbestiform talc as talc containing asbestiform 9 "fibrous talc" but to non-asbestos fibers fibers, correct? 10 occurring in otherwise platy talc. 10 Those fibers in talc, yes. Again, <sup>11</sup> BY MR. HEGARTY: <sup>11</sup> for my expert report, which we'll -- which draws 12 You say in this paragraph 29 that: <sup>12</sup> regulatory obligation and self-regulatory conduct 13 <sup>13</sup> conclusions from the presence in talcum powder "Asbestiform talc is classified products of asbestos and asbestiform fibers, I am alongside asbestos in a 2012 IARC Monograph as <sup>15</sup> using the terms "asbestiform fibers," "talc carcinogenic to humans (Group 1) and causing <sup>16</sup> containing asbestiform fibers," and "fibrous talc" ovarian cancer." 17 to mean essentially the same thing. MR. HEGARTY: I marked as 18 If that is incorrect, I apologize, Exhibit No. 14 a copy of that 2012 19 monograph. I didn't bring an extra <sup>19</sup> but it's also something that's much more relevant 20 20 to, you know, a different expert's report than to copy --<sup>21</sup> mine. 21 DR. THOMPSON: That's all 22 22 For purposes of this part of your right. 23 MR. HEGARTY: -- because I report, you made reference to the expert report of 24 <sup>24</sup> Longo and Rigler that we mentioned earlier. couldn't carry it. Page 271 Page 273 1 Do you see that in paragraph -- in THE WITNESS: That was mine 2 footnote 7? (indicates). 3 3 (Document marked for A. Yes. identification as Sage Exhibit 14.) Q. Are you aware that they are paid plaintiffs' experts? BY MR. HEGARTY: 6 If you look over at page 219 of that MS. PARFITT: Objection. 7 monograph? Form. 8 A. Uh-huh. DR. THOMPSON: Objection. 9 9 Q. It says in the first paragraph Form. 10 THE WITNESS: Yes, I am. towards the bottom: "The conclusions reached in this BY MR. HEGARTY: <sup>12</sup> Monograph about asbestos and its carcinogenic 12 Are you aware that they've been paid <sup>13</sup> risks apply to these six types of fibres wherever 13 millions of dollars by the plaintiffs' lawyers in <sup>14</sup> they are found, and that includes talc containing the talc litigation? <sup>15</sup> asbestiform fibres." 15 DR. THOMPSON: Objection. 16 16 Do you see that? Form. 17 17 A. THE WITNESS: I do not know 18 18 Q. Are you equating or are you saying their compensation. that what you're saying referring to in this 19 BY MR. HEGARTY: paragraph is talc containing asbestiform fibers? 20 Are you aware that they have not 21 DR. THOMPSON: Object to form. published their findings in any peer-reviewed <sup>22</sup> BY MR. HEGARTY: 22 journal? 23 In other words, are what you're DR. THOMPSON: Objection. 24 <sup>24</sup> calling asbestiform talc, talc containing Form.

Page 276 1 1 report? THE WITNESS: I was not aware 2 2 A. I don't recall, honestly. of that. <sup>3</sup> BY MR. HEGARTY: Would you like to have seen such Q. What did you do, if anything, to expert reports if they exist? assess the validity of the findings of Drs. Longo I would be happy to consider them. Did you ask for any defense expert and Rigler? 7 <sup>7</sup> reports commenting on the processes and procedures DR. THOMPSON: Objection. 8 and reliability of the findings of Drs. Longo and Form. 9 <sup>9</sup> Rigler in their report? THE WITNESS: With reference 10 to asbestiform fibers in talc, the -- the 10 On those, I don't believe I saw the 11 <sup>11</sup> defense perspective. Though it may have been way I approached a lot of the medical and 12 scientific evidence in formulating my covered in the Health Canada submission from 13 opinions involve looking for multiple <sup>13</sup> Johnson & Johnson or in similar documentation. 14 consistent sources of the same <sup>14</sup> Obviously, there was a lot of back and forth about 15 <sup>15</sup> testing standards and the reliability of results, information. 16 And certainly with respect to and to the extent I needed to consider those to 17 the presence of asbestos in talc, I saw formulate my own regulatory opinions, I considered 18 18 them. multiple consistent sources, of which the 19 19 Longo reports were only one. In paragraph 30, you refer to a 20 BY MR. HEGARTY: 20 document you call "Hopkins 28." 21 21 Do you have the expertise to Do you see that? 22 <sup>22</sup> evaluate the testing that they did for its Yes. Α. 23 reliability? MR. HEGARTY: I'm going to 24 24 mark as Exhibit No. 15 the Hopkins 28 DR. THOMPSON: Objection. Page 277 Page 275 Form. document. 2 2 THE WITNESS: I have the (Document marked for 3 3 expertise to read descriptions of testing identification as Sage Exhibit 15.) 4 approaches, and insofar as there's BY MR. HEGARTY: 5 Does that look familiar to you? information presented about the O. 6 advantages or disadvantages compared to 6 A. Yes, it does. 7 other testing approaches, I can reach a Do you know who created this O. 8 8 general conclusion that would be at a document? 9 9 higher level than a layperson. A. I believe I was told, but I can't <sup>10</sup> BY MR. HEGARTY: recall right now. 11 Did you do anything independently to Do you know that this document was assess the reliability of the findings reported in created by plaintiffs' counsel in this case? 13 13 the report by Drs. Longo and Rigler you cite here? DR. THOMPSON: Objection. 14 14 Independently, no. Form. Misstates. 15 15 DR. THOMPSON: Objection. THE WITNESS: I don't know 16 16 this. I mean, it's a -- it's a synthesis Form. 17 17 THE WITNESS: But they were and it is an exhibit. It doesn't have 18 18 consistent with -- at least specifically any other markings on it that would tell 19 19 with respect to asbestos content, they me where it comes from. 20 were consistent with other sources. 20 BY MR. HEGARTY: 21 <sup>21</sup> BY MR. HEGARTY: O. Who is Hopkins? 22 22 Were you provided with any expert I was told that, and right now at reports by Johnson & Johnson's experts as it this point in this deposition I'm afraid I can't <sup>24</sup> relates to commentary on Drs. Rigler and Longo's <sup>24</sup> -- I can't remember.

Page 280 1 What I -- what I do remember about

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<sup>2</sup> this is that this was one of the confirmatory

<sup>3</sup> sources of information about asbestos risk in --

<sup>4</sup> in baby powder products, and there was a

<sup>5</sup> back-and-forth between, I guess, Mr. Hopkins and

<sup>6</sup> defense experts as to whether these internal

<sup>7</sup> Johnson & Johnson reports were actually asbestos

<sup>8</sup> or were not asbestos, using the standards that

<sup>9</sup> Johnson & Johnson applied.

10 And I was also shown a subsequent

<sup>11</sup> document where I imagine it was Mr. Hopkins who

12 went back and responded to the defense's

<sup>13</sup> objections to certain characterizations, and I'm

<sup>14</sup> afraid that's the best I can do today in

<sup>15</sup> remembering this particular document.

16 Did you cite that other document <sup>17</sup> that you called a responsive document in your 18 report?

19 No. I believe I was shown that

20 responsive document subsequently to final --

21 Q. Shown by -- I'm sorry.

22 -- to finalizing the report. A.

23 Shown by whom? Q.

24 Α. Shown -- shown my plaintiffs'

independently confirm. This compilation 2 was something that I looked at and 3

thought about and discussed and saw the

defendants' position on.

BY MR. HEGARTY:

Q. You took this document at face value, correct?

DR. THOMPSON: Object to form.

THE WITNESS: I took this document as being an accurate list of dates and internal testing and results.

BY MR. HEGARTY:

13 If this document is inaccurate, you agree that that can affect your opinions in this 15 case, correct?

DR. THOMPSON: Objection. THE WITNESS: No, I don't think my -- my opinions, again, considering the totality of the opinions and the other sources of evidence of asbestos adulteration in baby powder products, I don't think my opinions stand on or fall on this or any other single document.

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<sup>1</sup> counsel in a discussion about asbestos content.

This document makes reference to <sup>3</sup> other exhibits.

Did you review the documents that <sup>5</sup> this exhibit references, the actual documents 6 themselves?

A. No.

It was evident that such documents <sup>9</sup> would exist because this was a compilation of

<sup>10</sup> documents.

14

11 Do you see on the very first line of

12 Exhibit or -- I'm sorry -- the line in Exhibit

<sup>13</sup> No. 28 that's dated a 5/9/1958?

Do you see that line?

15 (Laugh). Unless we want to declare <sup>16</sup> a brief recess for me to get a magnifying glass

from my briefcase, I'm having trouble reading this

particular document.

19 Needless to say, though, you did not independently confirm whether any of the documents

<sup>21</sup> that are referenced here actually show asbestos in

<sup>22</sup> Johnson's Baby Powder, correct?

23 DR. THOMPSON: Object to form.

24 THE WITNESS: I did not <sup>1</sup> BY MR. HEGARTY:

Again, you make reference in this <sup>3</sup> paragraph to what we talked about earlier, the <sup>4</sup> report of Drs. Longo and Rigler.

Did you do any analysis yourself as <sup>6</sup> far as where they obtained the product that they <sup>7</sup> tested and whose results they reported in this --

in this report? 9

A. No.

You also make reference in this

paragraph, as you mentioned earlier, to FDA's 2019 12 testing.

13 Do you see that?

14 I'm sorry. I was taking a drink of

water. Hold on.

16

Q. That's all right.

17 A. Yes, of course.

18 Q. And did you actually review the

testing document from the lab that FDA relied upon to report that finding?

I believe that document was

<sup>22</sup> available. I most remember reviewing FDA's press

<sup>23</sup> releases and other public statements at the time

<sup>24</sup> of their testing and -- and their findings and

Page 284 <sup>1</sup> what became, thankfully, voluntary recalls of the <sup>1</sup> this being reported, correct? <sup>2</sup> products involved. I am aware of -- of some of this Do you recall what type of asbestos <sup>3</sup> being reported, yes. <sup>4</sup> FDA claimed to have found pursuant to its testing Do you agree that the testing that <sup>5</sup> results --<sup>5</sup> was done calls -- by Johnson & Johnson calls into question the accuracy of the FDA testing results? A. No. 7 DR. THOMPSON: Objection. Q. -- testing procedures? 8 No, I don't at the moment. 8 Form. 9 9 MR. HEGARTY: I'm going to THE WITNESS: I don't have a 10 10 mark as Exhibit No. 16 a statement by basis to agree with that. 11 11 Johnson & Johnson of December 3, 2019. If the FDA had retracted its 12 12 (Document marked for findings, then I would have a basis; but, 13 13 identification as Sage Exhibit 16.) again, the core of my analysis is a 14 <sup>14</sup> BY MR. HEGARTY: regulatory analysis, and I'm not offering 15 15 an expert opinion as to causation or as Q. Is this the first time you've ever 16 16 seen this? to any particular set of -- of product 17 17 I was aware that Johnson & Johnson tests. <sup>18</sup> had done its own testing of a number of samples 18 BY MR. HEGARTY: and had found no asbestos using its standards. I 19 You did not make any reference to <sup>20</sup> do think this is the first time I've seen this any follow-up testing done by Johnson & Johnson in your report, correct? 21 press release. 22 22 Α. Do you see in this document I don't believe so. 23 <sup>23</sup> number -- Exhibit No. 16 the third paragraph says You also did not make reference to 24 that: <sup>24</sup> testing done by FDA in 2009 and 2010 of Johnson's Page 285 Page 283 "The Company's investigation <sup>1</sup> Baby Powder finding no asbestos, did you? <sup>2</sup> included that the most probable root causes for DR. THOMPSON: Object to form. 3 <sup>3</sup> the FDA's reported results were either test sample THE WITNESS: My recollection 4 <sup>4</sup> contamination and/or analyst error at the AMA of that -- and, you know, bear with me 5 <sup>5</sup> lab." complicated topic -- is that those were 6 Do you see where I'm reading from? 6 tests of a rather small number of 7 I just -- just one moment. I'm samples; and, no, I did not make A. <sup>8</sup> seeing -- I'm seeing a similar statement in the 8 reference to those. <sup>9</sup> "Over the course of the investigation" paragraph. BY MR. HEGARTY: <sup>10</sup> Is that where you're reading from? 10 Well, you made reference to the 2019 11 I was reading from the third 11 Q. testing by FDA. 12 <sup>12</sup> paragraph. Why did you not make reference to 13 the 2009 testing by FDA? A. Oh. 14 The first page. DR. THOMPSON: Object to form. O. 15 15 A. Oh, I'm sorry, yes. Yes. THE WITNESS: Because the 16 Okay. And then do you see a couple 16 2019 testing resulted in regulatory paragraphs down where the statement notes that 155 17 action and rose to the level that was <sup>18</sup> tests conducted by two different third-party labs 18 something widely reported and in my confirmed that there is no asbestos in that 19 opinion reliable. 20 product? 20 BY MR. HEGARTY: 21 21 Do you see that? Well, you mentioned a moment ago 22 that you recall that the 2009 test results were of I see that assertion. A. 23 And you said prior to seeing this a small number of samples. 24 statement that you were aware at least of some of 24 Do you understand that the 2019 test

Page 288 <sup>1</sup> result was from a single bottle of Johnson's Baby I'm not expressing an expert opinion <sup>2</sup> Powder? <sup>2</sup> as -- as to who wins that particular argument; but DR. THOMPSON: Object to form. <sup>3</sup> if there is asbestos in baby powder in one bottle, 4 THE WITNESS: I understand <sup>4</sup> it is unlikely that there is no asbestos in any 5 other bottle in an entire global production. that the positive result was a single 6 bottle, but recall that if you're trying That's not my question. 7 to prove a negative and you test -- I'm My question is: If -- under your 8 making up a number -- five bottles of standard if every test that has been done on 9 Johnson's Baby Powder showed no asbestos, you baby powder and don't find asbestos, 10 that's not going to be evidence that no would still not believe that that was sufficient 11 to prove that Johnson's Baby Powder doesn't have bottle has asbestos. 12 I suspect with regard to the asbestos in it, correct? 13 13 2019 testing that if we multiplied one MS. PARFITT: Objection. 14 14 asbestos-laden bottle out to the full DR. THOMPSON: Object to form. 15 15 number of bottles of baby powder that THE WITNESS: My belief in 16 16 Johnson & Johnson sold that year, I doubt some sense is irrelevant here. 17 17 that your client would -- would decide I have documentary evidence of 18 18 that, you know, we'd have to see how many asbestos in baby powder and that is 19 19 bottles -- was it 50 some that Johnson & highly relevant to my regulatory 20 20 conclusions. Johnson -- that FDA tested? 21 21 But, I mean, if we -- if we I have seen many documents 22 22 that cast doubt on the sufficiency of a divide your total production by 50 and 23 23 multiply that number by 1 and said long-time testing standard for asbestos 24 24 that's -- that's how many asbestos-laden in terms of actually determining whether Page 287 Page 289 1 bottles of baby powder in the market, I there is asbestos or, for that matter, 2 2 don't think your client would be asbestiform fibers in baby powder 3 3 comfortable with that. You know, this is products or has been over the years, 4 4 not scientifically comparable, a negative which has understandably produced in me 5 5 finding in three bottles. some skepticism around negative findings. 6 6 May not be applicable to these If we want to do positive 7 7 particular assays because I can't weight predictive value and negative predictive 8 8 value calculations, these two are not the details on short notice, but I think 9 9 comparable pieces of logic. I am no more demanding of Johnson & <sup>10</sup> BY MR. HEGARTY: 10 Johnson than the law and the regulations 11 11 Well, according to your analysis, a expect me to be. <sup>12</sup> negative finding in every bottle tested would 12 BY MR. HEGARTY: 13 still not be enough under your standard to prove You do not have the expertise to <sup>14</sup> that talcum powder products don't contain comment on how much asbestos exposure can cause asbestos, correct? ovarian cancer, correct? 16 16 DR. THOMPSON: Object. That ---17 17 DR. THOMPSON: Object to form. THE WITNESS: I do not, but 18 18 THE WITNESS: That's there is a consensus among experts and 19 19 regulatory authorities that the presence incorrect. 20 BY MR. HEGARTY: 20 of asbestos in consumer products is an 21 21 Q. How is that incorrect? adulterant and is hazardous to health. 22 BY MR. HEGARTY: 22 The FDA used its laboratories and <sup>23</sup> its laboratory standards. Johnson & Johnson used 23 If you look at paragraph 31, you <sup>24</sup> others and disagreed with the FDA's finding. <sup>24</sup> comment on fragrances.

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And before being hired by

- <sup>2</sup> plaintiffs, have you ever commented on fragrances
- <sup>3</sup> in a consumer product?
- I have never commented on
- <sup>5</sup> fragrances.
- Your entire -- your sole reference
- <sup>7</sup> in this paragraph is to an expert report of
- <sup>8</sup> Dr. Crowley.
- Did you read that report in its <sup>10</sup> entirety?
- In its entirety, no. I did look at
- 12 it, and the purpose of this is that consistent
- 13 with current FDA requirements, fragrance-related
- <sup>14</sup> disclosures for cosmetics are limited as a
- <sup>15</sup> fragrance being something that is often of great
- <sup>16</sup> proprietary value to the company making the
- <sup>17</sup> product.
- 18 I have -- I would have preference
- <sup>19</sup> for greater disclosure of fragrance-related
- <sup>20</sup> ingredients, but the purpose of including
- <sup>21</sup> paragraph 31 is that there are many ingredients in
- <sup>22</sup> talcum powder products beyond what's listed on the
- <sup>23</sup> label.

3

7

8

9

A.

<sup>6</sup> Exhibit 47.

24 Q. You did not do your own independent

<sup>2</sup> fragrances in Johnson's Baby Powder, correct?

- <sup>1</sup> BY MR. HEGARTY:
  - O. Does that exhibit look familiar to
- <sup>3</sup> you?
- In passing, yes. I don't think I
- spent much time looking at this.
- Did you look at the individual
- documents from which this document was prepared?
- No. I just looked at the list of,
- you know, as presented here in the substances that
- were -- that were present in -- in these samples
- as a confirmation that indeed there are materials
- here that in some instances, in some doses, in
- some exposures are known to have health hazards.
- But I'm not making -- the same way
- 15 I'm not offering an opinion as a scientific
- <sup>16</sup> expert as to whether, you know, talcum powder
- exposure causes ovarian cancer, I'm not offering a
- <sup>18</sup> scientific opinion on the causal connection
- <sup>19</sup> between any one of these particular ingredients
- and any particular health injury.
- 21 Q. Do you know who prepared this
- <sup>22</sup> document?
- I would assume this is also a --
- <sup>24</sup> well, actually, no, I don't know. I would

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- <sup>1</sup> assessment of any risk associated with any of the <sup>1</sup> assume -- I would assume this is also a
  - <sup>2</sup> plaintiffs' exhibit or a plaintiffs' document, but
  - <sup>3</sup> I don't know.
- If you look over at paragraph 32 of <sup>5</sup> your report, you cite in that paragraph to a Pier

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- Yes, and this was, you know, in

  - and other -- other potential contaminants or
- Who is Pier? Q.
- 10 I cannot recall. A.
- 11 What's her name? Do you know what
- <sup>12</sup> her name is? First name?

Yes.

Correct.

Do you see that?

- 13 A. No.
- 14 Is she employed by Johnson & Q.
- 15 Johnson?
- 16 I would have to go back and -- and 17 look at the exhibits.
- 18 Q. Did you read her deposition?
- 19 I can't recall.
- 2.0 MR. HEGARTY: I'm going to
- 21 mark as Exhibit 17 the Pier exhibit that 22
- you cite in this paragraph.
- 23 (Document marked for 24 identification as Sage Exhibit 17.)

- - And plaintiffs' lawyers provided you
- with this Exhibit Pier 47 and Hopkins 28, correct?
- <sup>7</sup> response to my request about having metal content
- adulterants of -- of baby powder products.
- Did you independently investigate
- any or independently assess the literature as it
- relates to heavy metals and the risk of ovarian 13 cancer?
- 14 I did not. I considered these risks
- <sup>15</sup> worth mentioning in light of the regulatory
- obligations, but less certain in their hazardous
- consequences than asbestos, which is why I would
- sort of go back to the bold heading above all of
- these paragraphs which says "Contain or may
- <sup>20</sup> contain ingredients that pose health hazards to
- <sup>21</sup> consumers."
- 22 You did no independent assessment as
- <sup>23</sup> far as whether there are heavy metals in Johnson's
- <sup>24</sup> Baby Powder, correct?

Page 294 Page 296 1 Q. Does EPA allow levels of asbestos in A. Correct. 2 drinking water? O. You did no assessment, to the extent <sup>3</sup> there are any such materials in Johnson's Baby DR. THOMPSON: Object to form. <sup>4</sup> Powder, as far as the extent of any such THE WITNESS: I do not know. <sup>5</sup> materials, correct? BY MR. HEGARTY: If we look next at --In terms of concentrations and O. <sup>7</sup> overall prevalence and likelihood of exposure, no. I would say that, you know, You did not read any medical 8 ingestation of asbestos has never been a root of <sup>9</sup> literature as it relates to exposure to these <sup>9</sup> exposure that I have seen to be frequently <sup>10</sup> associated with a health hazard. It doesn't mean heavy metals and cancer risk, correct? DR. THOMPSON: Object to form. 11 it couldn't be. Very similar in some ways to 12 THE WITNESS: I can't -- I radon exposure. 13 13 can't recall. It wouldn't have been --O. If you look next at paragraph 42. 14 14 it wasn't the focus of any of the A. 15 15 What is your authority for the scientific literature that I reviewed. Q. 16 It might well have been mentioned in <sup>16</sup> definition of risk that you have in that 17 passing. paragraph? 18 18 This is -- this is from my BY MR. HEGARTY: 19 <sup>19</sup> longstanding expertise in risk regulation and risk You reference -- or strike that. assessment, and this -- this is a, I would say, 20 There are monographs that refer to <sup>21</sup> majority view makes a distinction between risk and 21 these heavy metals. 22 Did you review the monographs for <sup>22</sup> uncertainty. It is, again, a distinction that is <sup>23</sup> made for purposes of analysis and purposes of these heavy metals by IARC? 24 Did I review an IARC heavy metal <sup>24</sup> regulatory action. A. Page 295 Page 297 <sup>1</sup> monograph? Not in any detail and perhaps not at It is -- it's not a matter of <sup>2</sup> all. I can't recall. <sup>2</sup> scientific fact. Most of this comes out of the Q. If you look over next at paragraph <sup>3</sup> economics literature. Some economists use the <sup>4</sup> 39, you say that: <sup>4</sup> umbrella term "risk" to describe both known "Current literature suggests that probabilities and unknown aspects of those <sup>6</sup> there is no safe level of asbestos." probabilities. I would say more economists do what Do you see where I'm reading? 8 I have done here and make a distinction for A. 9 discussion purposes between risk and uncertainty, Q. Do you understand that there are <sup>10</sup> background levels of asbestos in urban and other and I think that that distinction is essential to areas of the United States? these opinions because there's a specific 12 DR. THOMPSON: Object to form. regulatory requirement, as you know, that 13 THE WITNESS: I did not know uncertainty be disclosed in connection with 14 that. It would not surprise me. cosmetic safety. 15 15 BY MR. HEGARTY: If we look at paragraph 45, you say: 16 16 "Both the risk and the uncertainty In your -- I'm sorry. Go ahead. O. 17 A. I'm done. must be disclosed under law." 18 18 O. In your opinion, do background First, to what law are you 19 levels of asbestos in the air cause ovarian 19 referring? So -- so with respect to cosmetics, cancer? 21 <sup>21</sup> you have these statutory pillars of adulteration DR. THOMPSON: Object to form. 22 THE WITNESS: I have no basis <sup>22</sup> and misbranding because you don't have that much <sup>23</sup> more. 23 for giving an opinion on that.

24

<sup>24</sup> BY MR. HEGARTY:

And then in terms of FDA regulation

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17

<sup>1</sup> that's in the CFR, you have both 740.1 part A in

<sup>2</sup> terms of warning labels. "Labels shall bear a

<sup>3</sup> warning statement wherever necessary or

<sup>4</sup> appropriate to prevent the health hazard that may

<sup>5</sup> be associated with the product." You know, "may

<sup>6</sup> be associated" clearly encompasses risks.

And then you have this really belt

<sup>8</sup> and suspenders and, I think, extremely important

provision of 740.10(a), which -- which emphasizes

<sup>10</sup> the manufacturer's independent obligation to

<sup>11</sup> adequately substantiate safety of -- of cosmetic

<sup>12</sup> products and ingredients prior to marketing.

13 And then says that anything that has

<sup>14</sup> not been adequately substantiated -- meaning we

<sup>15</sup> don't know what the -- the risks, or lack of

<sup>16</sup> risks, are or the warnings or instructions that

17 might accompany them -- has to bear this

<sup>18</sup> additional specified statement that the safety of

<sup>19</sup> this product has not been determined.

20 Have you ever in any written

<sup>21</sup> document of yours prior to your expert report made

22 the statement that with regard to the cosmetic

<sup>23</sup> statutes and regulations both the risk and

<sup>24</sup> uncertainty must be disclosed?

If you just give me a moment.

Yes.

Can you cite for me any Johnson & Q. <sup>4</sup> Johnson employee who has ever expressed the view

that there is risk and uncertainty regarding talc

and ovarian cancer?

DR. THOMPSON: Object to form.

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THE WITNESS: I believe I

have seen some documentation regarding to use a nonscientific term "queasiness" on the part of Johnson & Johnson employees regarding the possibility that baby

13 powder is not safe applied perineally in

14 terms of ovarian cancer risk.

Is that a description of risk and uncertainty? I think so, but you might not.

18 BY MR. HEGARTY:

19 Q. Do you cite that document in this 20 report?

21 No. In terms of corporate -- I make

<sup>22</sup> no claims about corporate motive. And when I use

corporate knowledge, I'm really talking about

<sup>24</sup> notice, and there has been, you know, 50 years of

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DR. THOMPSON: Object to form.

THE WITNESS: No.

<sup>3</sup> BY MR. HEGARTY:

Can you cite for me a statement by <sup>5</sup> anyone in any publication prior to you writing

<sup>6</sup> your expert report where they said that with

<sup>7</sup> regard to the cosmetic statutes and regulations <sup>8</sup> both the risk and uncertainty must be disclosed?

DR. THOMPSON: Object to form.

10 THE WITNESS: Using those

11 terms?

12 BY MR. HEGARTY:

13 Q. Correct.

14 No, but those concepts, absolutely.

<sup>15</sup> The notion of a health hazard is a probabilistic

<sup>16</sup> determination and that is a risk, and the 740.10

<sup>17</sup> obligation, which has been referenced in many

<sup>18</sup> settings over the years since the 1970s when it

was put into regulation, is uncertainty. 19

You make the statement over on page

<sup>21</sup> 7 that "Johnson & Johnson has known about risk and

<sup>22</sup> uncertainty regarding talc and ovarian cancer for

<sup>23</sup> decades." 24

Do you see where I'm reading?

<sup>1</sup> scientific literature raising concerns about

<sup>2</sup> various aspects of talc and its potential or

<sup>3</sup> actual adulterants and cancer risk.

You've never spoken to anyone at

<sup>5</sup> Johnson & Johnson regarding talcum powder

products, correct?

A. Correct.

If we look over at paragraph 47, you

state in the first line:

"Johnson & Johnson's resistance to

the presence in talcum powder products of fibrous constituents that pose risk to human health is

strikingly at odds with the factual history."

You say "Johnson & Johnson's

15 resistance." To whom at Johnson & Johnson are you 16 referring to?

22

I'm referring to the persistent

unwillingness in the context that I have examined,

including this litigation, of Johnson & Johnson to

make any concession whatsoever regarding the lack

of evidence of safety for its legacy product.

Are you able to -- strike that.

23 Are you commenting on any individual

<sup>24</sup> person's view or opinion at Johnson & Johnson in

Page 302 Page 304 1 your report? that might be resulting from powder on 2 gloves. One could have granulomatosis If we were to look at Facts About <sup>3</sup> Talc, either the depository of documents or the 3 and other types of inflammation. <sup>4</sup> consumer-facing reassurances, it makes no <sup>4</sup> BY MR. HEGARTY: <sup>5</sup> concession even to uncertainty, which I actually But you're also aware that the FDA <sup>6</sup> find disappointing, frankly shocking, and directly <sup>6</sup> action was not based on any concern about cancer <sup>7</sup> at odds with its regulatory obligations. risk from particles on surgical gloves, correct? That didn't answer my question. DR. THOMPSON: Object to form. 9 Do you rely on any individual THE WITNESS: I would be person's statements at Johnson & Johnson for any 10 interested in reviewing the details of of the statements in your report? 11 that determination. I don't know for a 12 12 DR. THOMPSON: Object to form. fact that cancer was not a consideration, 13 THE WITNESS: I would -- do I 13 but it certainly wasn't the most pressing 14 14 consideration for surgical gloves. -- again, I have considered statements of 15 many employees. Do I cite any particular BY MR. HEGARTY: 16 individual or today do I recall the 16 O. Does corn starch present a risk of 17 17 individual as being particularly cancer? 18 18 important to my conclusions? No. To my knowledge, no. Α. BY MR. HEGARTY: 19 I believe the difference is that 20 corn starch can cause acute but not chronic In paragraph 48, you state: 21 "Johnson & Johnson Laboratories inflammation, and typically it's a chronic <sup>22</sup> recognized the inflammatory effects of talcum inflammatory process that's considered a powder in the peritoneal cavity." contributor to carcinogenesis. 24 24 And you cite as support an article Q. If you look over at paragraph 52 of Page 305 Page 303 <sup>1</sup> by Eberl. <sup>1</sup> your report, you make reference there to the "J4-1 2 method of asbestos detection." Do you see that? 3 Yes. 3 Do you see that? A. 4 0. Did you find this article yourself A. I do. 5 through any search you did? What is the J4-1 method? O. 6 6 A. No. A. The J4-1 method, based on the <sup>7</sup> documents I've reviewed, was an industry-based You know that that article makes no standard that was developed in part to forestall a reference to cancer risk, correct? more direct governmental or quasi-governmental I do know. It has to do with talcum standard setting process for asbestos testing. powder on gloves and surgical inflammation. 11 Are you aware that FDA has banned And it has been apparently controversial in this <sup>12</sup> any type of powder, including corn starch, on <sup>12</sup> litigation and other contexts of determining 13 gloves? <sup>13</sup> whether something that is undetectable asbestos is 14 actually no asbestos. I am aware that those -- that powder <sup>15</sup> is not used on gloves. Again, surgical gloves are 15 What testing methods should be used <sup>16</sup> not cosmetics and, yes, I do believe that was an 16 under the J4-1 method? 17 <sup>17</sup> FDA decision. DR. THOMPSON: Object to form. 18 18 And you know that Eberl and the FDA THE WITNESS: I remember this 19 <sup>19</sup> decision was based on the potential for powder on was light microscopy and some other gloves to cause adhesions or fibrosis 20 things. I don't remember the details 21 post-surgery, right? right now. I've read the specifications, 22 DR. THOMPSON: Object to form. 22 but I can't recall. 23 THE WITNESS: I believe <sup>23</sup> BY MR. HEGARTY: 24 24 adhesions are one of several conditions O. What's the level of detection

Page 306 Page 308 <sup>1</sup> under -- of asbestos under the J4-1 method? <sup>1</sup> BY MR. HEGARTY: DR. THOMPSON: Object to form. As far as what documents you did 3 THE WITNESS: That was hard <sup>3</sup> review, those were documents provided to you by 4 to assess from what I read because I read plaintiffs' counsel, correct? 5 correspondence with FDA and I believe A. Yes. 6 some internal perhaps corporate documents 0. Did you make any specific requests 7 that -- that talked about sort of one <sup>7</sup> for particular documents about the development of 8 percent thresholds and half percent the J4-1 method to plaintiffs' counsel? 9 A. thresholds. 10 10 And it was never actually O. Paragraph 54 refers to or you make 11 -- you make the statement in paragraph 54 that: clear to me exactly what was being --12 12 what was being measured in those; but "Condom manufacturers voluntarily 13 there was, it seemed, some debate about removed talc from their products because of 14 ovarian cancer concerns." whether those sensitivities were actually 15 15 sufficient to declare some -- a talc --And you cite in that at the end of 16 talcum powder product asbestos-free with that paragraph footnote 19, which is a document 17 PCPC MDL00062175. industry asserting that they were 18 18 sufficient and others asserting they were Do you see that? 19 19 I see that. not. 20 <sup>20</sup> BY MR. HEGARTY: MR. HEGARTY: I'm going to 21 21 How does the J4-1 method compare to mark as Exhibit 18 that very document you <sup>22</sup> the method Johnson & Johnson employs to test its 22 cited there. 23 talcum powder products? (Document marked for 24 24 DR. THOMPSON: Object to form. identification as Sage Exhibit 18.) Page 307 Page 309 1 THE WITNESS: I do not -- I <sup>1</sup> BY MR. HEGARTY: 2 Can you show me in that document to do not know. <sup>3</sup> BY MR. HEGARTY: <sup>3</sup> what you're referring to as support for the Is it your belief that Johnson & <sup>4</sup> statement you make in paragraph 54? <sup>5</sup> Johnson uses only the J4-1 method to test its baby (Reviews document.) This is, as you know, a compilation powder? MS. PARFITT: Objection. <sup>7</sup> of papers. So it's -- unlike a single paper, it's 8 DR. THOMPSON: Object to form. very hard for me to review it quickly. 9 THE WITNESS: I would assume Q. Okay. 10 10 that Johnson & Johnson has advanced its So I would have to look through this 11 detection methods beyond the J4-1 method extensively for -- for that information. 12 12 today. Well, if you look over at page 15 13 BY MR. HEGARTY: <sup>13</sup> and 16 and 17, there are references there to the 14 <sup>14</sup> year of 1995, and you make reference to the year Have you investigated that issue? Q. 15 Have I investigated that? No. <sup>15</sup> 1995 in paragraph 54. <sup>16</sup> Again, the discussion of the J4-1 method related So which of those documents there <sup>17</sup> for purposes of my opinion mostly to the that include a date of 1995 did you rely upon to <sup>18</sup> regulatory climate. make the statement in paragraph 54? 19 19 Do you believe you reviewed all the I can't identify one now. I can --<sup>20</sup> documents that have been produced by all the <sup>20</sup> I can say that I discussed this particular <sup>21</sup> companies in this litigation as it relates to the <sup>21</sup> statement and particular issues of the motivations <sup>22</sup> development of the J4-1 method? <sup>22</sup> and concerns with respect to talcum powder on 23 <sup>23</sup> condoms with plaintiffs' counsel to -- to verify A. No. 24 <sup>24</sup> that I had the correct information, but I can't DR. THOMPSON: Object to form.

Page 312 <sup>1</sup> say -- I can't find the cite for you right now. <sup>1</sup> obligations. Is your authority for that statement It is my opinion that this website, <sup>3</sup> which is very much consumer-facing and consumer plaintiffs' counsel? 4 MS. PARFITT: Objection. <sup>4</sup> reassuring, is part of the labeling, if not the 5 <sup>5</sup> label, of talc containing baby powder. Much of Form. 6 <sup>6</sup> this being mooted by the fact that talc containing DR. THOMPSON: Objection. 7 <sup>7</sup> baby powder is no longer manufactured or sold in Form. 8 THE WITNESS: It did not <sup>8</sup> the United States and Canada, but, of course, 9 people outside there could access this website. occur to me that this was a controversial 10 10 My question is a little bit statement. I did my best to verify 11 <sup>11</sup> different. through plaintiffs' counsel that it was 12 accurate because I want to make sure that 12 And my question is: Do you intend 13 13 to testify in this lawsuit about the veracity, anything that I am putting in the report 14 <sup>14</sup> which you know the definition of veracity, of is accurate. But --15 <sup>15</sup> Johnson & Johnson? BY MR. HEGARTY: 16 Would you agree --16 I don't know the definition of 17 -- in retrospect, I would certainly veracity for the purpose of this question. prefer to be citing a direct voluntary 18 Well, you know the definition of reformulation document or a scientific study <sup>19</sup> veracity is the truthfulness, correct? You're a rather than this particular footnoted timeline. lawyer? 21 21 If we look over at paragraph 70. Yes. Yes, if we were to say Q. 22 <sup>22</sup> (laugh). I am a lawyer. Are we back in my report? 23 Right. You are a lawyer. Let me Back in your report, paragraph 70. Q. 24 <sup>24</sup> back -- let me start my question again. A. Sure. Page 311 Page 313 You make several claims of Johnson & You know as a lawyer what the word <sup>2</sup> Johnson being untruthful. <sup>2</sup> "veracity" means? If are we using veracity as a Are you saying that Johnson & <sup>4</sup> Johnson is lying on the talc -- the safety -- the <sup>4</sup> synonym for accuracy? It appears to me that your <sup>5</sup> Facts About Talc website? <sup>5</sup> question allies distinctions between Johnson & <sup>6</sup> Johnson's motivation and character and the A. I was not comfortable with the accuracy of information presented. <sup>7</sup> representations to consumers that Johnson & <sup>8</sup> Johnson made on that website with respect to I am -- it would be part of my <sup>9</sup> safety and purity, particularly the content and <sup>9</sup> testimony that the information presented is at <sup>10</sup> tone that suggests that these questions about odds with the required consumer-facing labeling of <sup>11</sup> potential health hazards have been definitively these products to be compliant with FDA 12 resolved. <sup>12</sup> regulations. 13 And my objections in the report are Do you intend to testify about the intent of Johnson & Johnson in regards to any

<sup>14</sup> most relevant to my conclusion that Johnson & <sup>15</sup> Johnson has not complied with its disclosure <sup>16</sup> obligations regarding safety not being <sup>17</sup> substantiated.

18 Well, do you intend to testify in <sup>19</sup> this litigation about the veracity of Johnson & Johnson as it relates to this website?

21 I would testify about the content of <sup>22</sup> this website and the ways in which this content is <sup>23</sup> at odds with Johnson & Johnson's self-regulatory <sup>24</sup> obligations and their specific regulatory

A.

website?

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17

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18 O. Do you intend to talk about the motives of anyone at Johnson & Johnson as it relates to talcum powder products?

document and, in particular, the Facts About Talc

Α. No.

22 Do you intend to testify that

<sup>23</sup> Johnson & Johnson in setting up the Facts About <sup>24</sup> Talc website did so to lie to the public about the

Page 314 Page 316 <sup>1</sup> safety of talc? <sup>1</sup> contention that the Facts About Talc website <sup>2</sup> failed to provide a balanced discussion of the I am a student of institutions both <sup>3</sup> governmental and corporate in these regulatory <sup>3</sup> medical and scientific literature on the subject <sup>4</sup> contexts. I am extremely interested in how a of talcum powder use and ovarian cancer? <sup>5</sup> company as large and as experienced and as DR. THOMPSON: Object to form. 6 <sup>6</sup> accomplished as Johnson & Johnson has been in many THE WITNESS: It's my opinion <sup>7</sup> domains could, in my opinion, fall so far short of 7 that the Facts About Talc website, 8 <sup>8</sup> its obligations in this respect. insofar as it is accessible to and easily 9 So would I offer a conclusion about findable by someone who's using Johnson's 10 <sup>10</sup> corporate motivation? No. Baby Powder and wondering whether there Were I to be questioned on it, might 11 is risk or uncertainty, it is my position 12 12 I offer thoughts about how this type of thing that in that connection, the website 13 might happen? I'm really shocked that this could 13 provides information that is at odds with <sup>14</sup> happen and that at this juncture between what is 14 Johnson & Johnson's regulatory 15 presented to consumers as a pure and proved safe 15 obligations. <sup>16</sup> product and the science and the regulatory <sup>16</sup> BY MR. HEGARTY: <sup>17</sup> obligation is very disturbing to me, and indeed 17 Do you have any opinion as to -- is 18 that's part of my report and would be part of my it your opinion that the Facts About Talc website <sup>19</sup> testimony. is not valid, fair and balanced? 20 20 You state that the website omits any DR. THOMPSON: Objection. <sup>21</sup> suggestion of uncertainty with respect to the 21 THE WITNESS: We're not 22 <sup>22</sup> overall safety or carcinogenic risk of talcum discussing Fox News. I do not see what 23 powder products. -- "fair and balanced" is not a phrase 24 24 Do you see where I'm reading? that I think relates to --Page 317 Page 315 Yes. That was my read of the <sup>1</sup> BY MR. HEGARTY: website as I encountered it personally. Okay. Let me use a different So your position is that a proper <sup>3</sup> phrase. <sup>4</sup> analysis of the issues of talc and ovarian cancer That's not -- by the way, Fox News <sup>5</sup> must include a discussion of all authorities on doesn't own the term "fair and balanced," right? They think they do, but we can leave the issue, correct? A. <sup>7</sup> that aside. (Laugh). MS. PARFITT: Objection. 8 DR. THOMPSON: Object to form. Well, is it your contention that the 9 <sup>9</sup> Facts About Talc website is misleading because it THE WITNESS: Would you 10 <sup>10</sup> doesn't include contrary scientific and medical repeat that? <sup>11</sup> literature as it relates to the safety of talcum 11 BY MR. HEGARTY: 12 powder products? O. Sure. 13 13 DR. THOMPSON: Object to form. So it's your position that a proper analysis of the issues of talc and ovarian cancer, 14 THE WITNESS: I'm doing my <sup>15</sup> including as it relates to the Facts About Talc 15 best to answer the questions you're website, should include a discussion of all the 16 asking. 17 17 authorities on the issue, correct? My -- my position is that, 18 DR. THOMPSON: Object to form. 18 first of all, the Facts About Talc 19 19 THE WITNESS: I am failing to website omits any disclosure of 20 see the connection between this question 20 uncertainty, which is a specific 21 21 and prior questions. So I think I don't regulatory obligation, and, frankly, is

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Well, is it your statement --

know how to answer it.

<sup>23</sup> BY MR. HEGARTY:

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so conclusory that it might even negate

that Johnson & Johnson might make.

some other statement about an uncertainty

Page 320 1 <sup>1</sup> BY MR. HEGARTY: uncertainty. 2 The only way to -- the only Have you read the JAMA O'Brien 2020 <sup>3</sup> article on talcum powder and ovarian cancer? 3 disagreement -- well, the only difference 4 I am pretty sure I have, but I would of opinion in terms of risk and <sup>5</sup> love to be refreshed on any one of these. 5 uncertainty is whether uncertainty is 6 You don't comment about that in your subsumed in risk in the -- in the <sup>7</sup> report, do you? 7 economics literature. 8 Again, presumably, you're asking me Once one teases the two things 9 <sup>9</sup> this because I -- because I don't. out, I mean, if we could put it in the 10 10 My -- my comments on the -- on the national defense context and talk about <sup>11</sup> scientific literature go through a timeline and 11 the known unknowns and the unknown 12 <sup>12</sup> looking at key studies, but I do believe I've seen unknowns, but the uncertainty is the 13 13 that. I'd love to see it again if you want to central regulatory obligation of 740.10. 14 show it to me. 14 So I don't need more authority 15 15 If you look at paragraph 71 of your than it's explicit in the regulation. <sup>16</sup> report, is your only authority for the statements BY MR. HEGARTY: <sup>17</sup> you make what you cite at the end "21 CFR 740.1 et My question is a little bit <sup>18</sup> seq."? different. Listen to my question, Doctor. 19 So it is a combination of the nature Is the word "uncertainty" used anywhere within 21 CFR 740.10 or anywhere in the <sup>20</sup> of cosmetics regulation compared to, say, the <sup>21</sup> nature of drug regulation, and a central aspect of cosmetic regulations? <sup>22</sup> my analysis and opinions is that these two MS. PARFITT: Objection. 22 23 DR. THOMPSON: Objection. <sup>23</sup> regulatory regimes are quite different. 24 24 Mostly because in the -- in terms of Form. Page 319 Page 321 <sup>1</sup> drug authorities, FDA's role, its preventive role THE WITNESS: No. <sup>2</sup> and all of its regulatory authorities are far more BY MR. HEGARTY: <sup>3</sup> detailed, far more self-executing, and are much For Johnson's Baby Powder, when <sup>4</sup> more consistent with a compliance mind-set among <sup>4</sup> should it have carried a risk of a warning -- when <sup>5</sup> the regulated entities. should it have carried a warning of a risk of Whereas, for cosmetics regulation, ovarian cancer? 7 <sup>7</sup> the principal obligations are informational and DR. THOMPSON: Object to form. <sup>8</sup> virtually all of the requirements are for 8 THE WITNESS: I think, at a 9 <sup>9</sup> self-regulation that results in safe products. minimum, by the early 1970s, it should 10 Can you cite for me any authority have carried a -- a warning of a 11 potential health hazard. That was saying that there is a low threshold for 12 12 disclosure risk? informed by what was already worrisome 13 That is my conclusion based on the literature on ovarian cancer risk. <sup>14</sup> lack of offsetting benefit for cosmetic, and that 14 BY MR. HEGARTY: 15 is -- and that's an established position in the 15 Should a cosmetic manufacturer warn <sup>16</sup> literature, but I don't cite specifically. 16 of a risk that does not exist? 17 17 And you already told us that you DR. THOMPSON: Object to form. cannot cite any authority in the regulatory 18 THE WITNESS: Again, a risk setting that uses the word "uncertainty" when it 19 is a known probability. If the known comes to the labeling of cosmetics, correct? 20 probability is zero, then there is no 21 21 DR. THOMPSON: Object to form. risk and there's no warning obligation. 22 22 THE WITNESS: Disagree in BY MR. HEGARTY: 23 23 that the 740.10 obligation is about Likewise, is a cosmetic -- is a 24 <sup>24</sup> cosmetic manufacturer required to warn about a safety not being determined, which is

Page 322 Page 324 1 <sup>1</sup> health hazard that does not exist? discussing and the reason we're here, 2 DR. THOMPSON: Object to form. there are many, many scientific studies 3 THE WITNESS: So to answer 3 that show non- -- non-1 confidence 4 4 these questions, best -- best to use the intervals that -- that raise, I think, actual regulatory language. So we can --5 indisputable concerns about possible 6 <sup>6</sup> BY MR. HEGARTY: health hazards which means 7 Well, do you need regulatory nonsubstantiation for safety. 8 8 language to say? Is there a definitive 9 Yes. Actually, when one is hierarchy? No, and it's going to be 10 paraphrasing an obligation, yeah. depend on context. But, you know, 11 So, you know, talks about "necessary something that has never been 12 or appropriate to prevent a health hazard that may studied that nobody is really thinking, 13 be associated with the product." much substantiation -- and there's no 14 So if you are saying that there is suggestion that there's an injury, <sup>15</sup> no probability, no possibility that a health 15 substantiation for safety may be 16 <sup>16</sup> hazard may be associated with a product, then accomplished in a relatively 17 there is no warning obligation. straightforward way. 18 18 Okay. If you look over at paragraph Q. But when we have good science <sup>19</sup> 77. 19 that shows a possible increased risk of a 20 20 substantial degree for a fatal disease Uh-huh. Α. 21 21 Q. You talk about 740.1 in that and we have this repeatedly over decades, 22 paragraph, correct? I don't think it's seriously in doubt 23 23 that -- that talcum powder products A. Correct. 24 24 Q. Can you cite for me any published haven't been substantiated for safety. Page 323 Page 325 <sup>1</sup> authorities that identify the studies that must be <sup>1</sup> BY MR. HEGARTY: <sup>2</sup> done to adequately substantiate the safety of a Listen to my question. That's not <sup>3</sup> product? <sup>3</sup> what I asked you, Doctor. 4 DR. THOMPSON: Object to form. You make reference to the 740.10(a) 5 <sup>5</sup> and talk about that "each ingredient used in a THE WITNESS: I'm sorry. I 6 think -- I think that the paragraph -- I <sup>6</sup> cosmetic and each finished cosmetic product shall 7 thought you said paragraph 77, which is <sup>7</sup> be adequately substantiated for safety prior to 8 marketing." about --My question is: Is there a written BY MR. HEGARTY: 10 published standard for what a manufacturer must --I'm sorry. 78. O. 11 for what tests a manufacturer of a cosmetic must All right. A. 12 <sup>12</sup> do to substantiate the safety of that product O. Look at paragraph 78. 13 Sorry about that. <sup>13</sup> before marketing? A. 14 14 Can you cite for me any published My opinion is that substantiation authority that identifies the study that must be <sup>15</sup> for safety is contextual, and that there have been done to adequately substantiate the safety of a statements from time to time in particular 17 cosmetic product? contexts, but nothing that I regard as definitive. 18 18 DR. THOMPSON: Object to form. O. The manufacturer must assess the 19 <sup>19</sup> studies and determine if the cosmetic safety is THE WITNESS: There are, I 20 believe, documents that nondefinitively substantiated, correct? 21 21 and nonexclusively and noncomprehensively Α. Correct. 22 22 suggest the sorts of things that could You understand that Johnson & 23 build into substantiation for safety. Johnson has repeatedly done so as to Johnson's 24 But remember what we've been <sup>24</sup> Baby Powder, Shower to Shower, correct?

Page 328 1 1 DR. THOMPSON: Object to form. DR. THOMPSON: Object to form. 2 2 THE WITNESS: I understand THE WITNESS: I don't believe 3 3 those are Johnson & Johnson's conclusions Johnson & Johnson has done that. 4 from the studies that it has done. <sup>4</sup> BY MR. HEGARTY: 5 It is also my understanding You disagree with Johnson & Johnson, 6 that Johnson & Johnson has not 6 correct? 7 participated actively in efforts to A. Correct. 8 further study its product. DR. THOMPSON: Object to form. 9 If we're just talking -- if BY MR. HEGARTY: 10 we're talking only about asbestos, that's 10 You're making your own subjective 11 judgment on whether safety has been substantiated, one piece of this. If we're talking 12 about the overall connections between 12 correct? 13 13 talc -- perineal use of talcum powder DR. THOMPSON: Object to form. 14 14 products and ovarian cancer, it goes way THE WITNESS: No. I am making 15 15 beyond asbestos testing. an expert determination based on many 16 <sup>16</sup> BY MR. HEGARTY: scientific determinations and compendia 17 17 Well, you have reviewed, as we and other regulatory judgments that raise 18 <sup>18</sup> talked earlier, about the 2020 Johnson's Baby persistent and serious questions about 19 Talcum Powder: A Comprehensive Review document 19 substantiation for safety, such that, no, 20 dated March 17, 2020, correct? I do not believe that substantiation for 21 21 A. Yes. safety has occurred. 22 22 O. That's the last document in the And I conclude that the 740.10 23 notebook you have in front of you, correct? obligation of disclosure of uncertainty 24 24 Correct. is operative. Page 327 Page 329 <sup>1</sup> BY MR. HEGARTY: And you -- have you reviewed the <sup>2</sup> testimony of Johnson & Johnson's chief medical And you think that a jury should <sup>3</sup> officer, Dr. Kuffner? <sup>3</sup> believe you over Johnson & Johnson where you first I did not read that -- if that was <sup>4</sup> started looking at this issue three months ago; is <sup>5</sup> that correct? <sup>5</sup> deposition testimony, I did not read that <sup>6</sup> deposition in detail. DR. THOMPSON: Objection. THE WITNESS: I think juries You understand that Johnson & Johnson currently and has always concluded that are entitled to conclude what juries 9 <sup>9</sup> its talcum powder products are safe and that the conclude. 10 safety is substantiated? I think the existence of this 11 11 DR. THOMPSON: Object to form. regulatory obligation and its connection 12 12 to the information environment that THE WITNESS: I clearly 13 13 Johnson & Johnson has created around this understand that is the company's 14 14 position. I do not understand the basis one legacy product is something from 15 15 for that judgment. which juries may draw exactly the <sup>16</sup> BY MR. HEGARTY: conclusion that I have. 17 17 The regulations and authorities you BY MR. HEGARTY: 18 cite all provide that the manufacturer is to make You have never in any publication of 19 19 yours cited to 21 CFR 740.1, correct? this determination. 20 You understand that, right? 20 Are we on .1 or .10? But the answer 21 <sup>21</sup> would be for both of them, no. That's not a statement of deference. <sup>22</sup> That's a statement of obligation. 22 And you've never given a 23 Johnson & Johnson has done so. presentation where you have talked about 21 CFR

You understand that?

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<sup>24</sup> 740.1 or 740.10, or any cosmetic regulation that

Page 330 Page 332 What was it about the '70s from your <sup>1</sup> you're talking about in this report, correct? 2 <sup>2</sup> standpoint would have triggered the need to Correct. 3 <sup>3</sup> provide a warning with regard to health risk with MR. HEGARTY: Let's go ahead 4 and take a break. <sup>4</sup> talcum powder products? 5 (Recess: 3:02 p.m. -So as you know, in the 1970s, cancer 6 <sup>6</sup> risks from asbestos became, you know, of general 3:17 p.m.) 7 MR. HEGARTY: We are back on <sup>7</sup> concern, but environmental cancer risks became a general concern. Going into the history of the record. cancer, this is the period, and it's no BY MR. HEGARTY: coincidence that this is, you know, the Nixon 10 I wanted to look at next -- look <sup>11</sup> Administration's, you know, the EPA, motor vehicle next at paragraph 81 of your expert report. 12 A. Uh-huh. <sup>12</sup> safety. There's a whole bunch of sort of kind of 13 In the first line of that paragraph 13 post-NASA investments in scientific-based health Q. and safety regulations, the OSHA Act, the 14 you say that: 15 "Johnson & Johnson has a legal duty <sup>15</sup> Occupational Safety and Health Act. 16 to account -- to take account of 'new information' So, you know, this is a period when putting the safety of its talcum powder products people are looking at potential environmental <sup>18</sup> in question, even if the information is itself not <sup>18</sup> triggers for various cancers, and that's when many conclusive." of these studies are done. And more of them are 20 being done, and they're not motivated by anything What is the authority for or what is <sup>21</sup> the legal duty? Where -- what statute, what <sup>21</sup> other than genuine scientific curiosity on about <sup>22</sup> regulation where that legal duty found? <sup>22</sup> environmental exposure and its health 23 A. Okay. So that -- that authority <sup>23</sup> consequences. <sup>24</sup> comes -- comes right out of 740.10(b), you know, Q. Assume for purpose of my question Page 333 Page 331 <sup>1</sup> it's in the appendix on page 39 of the report that <sup>1</sup> that there is no asbestos in talcum powder <sup>2</sup> says "An ingredient or product may at any time <sup>2</sup> products. 3 <sup>3</sup> have its safety brought into question by new Would that change your opinions in 4 this case? <sup>4</sup> information that is itself not conclusive." 5 DR. THOMPSON: Object to form. O. Okav. And that's intended to convey an 6 THE WITNESS: If, in fact, A. <sup>7</sup> ongoing duty of the manufacturer to substantiate there were zero fibers of asbestos or of <sup>8</sup> safety. We're not talking about a one-shot, and 8 asbestiform talc in products, it would <sup>9</sup> meaning specifically that new information that 9 change some, but not all, of my opinions; 10 10 might suggest that -- that the prior assumed and it certainly would not change my 11 <sup>11</sup> substantiation was inaccurate needs to be taken opinions regarding nonsubstantiation for <sup>12</sup> account of and a decision, again, made whether to 12 safety. 13 BY MR. HEGARTY: <sup>13</sup> disclose that safety hasn't been determined. In paragraph 85, you make reference And this is exactly the sorts of 15 thing you would expect to become operative in a to the IARC Monograph 100C, which we marked and is <sup>16</sup> situation like ovarian cancer developing from -sitting to your right, and you make the statement <sup>17</sup> from -- from talcum powder in that we have latency in that paragraph that says that: <sup>18</sup> and a relatively uncommon condition and, you know, "The Monograph provides a detailed 19 something that might have appeared safe in, you <sup>19</sup> discussion of occupational exposures to asbestos <sup>20</sup> know, 1950 might not appear safe by, you know, and talc in which inhalation presents the primary <sup>21</sup> 1975. exposure, but this is not the only purpose." 22 And you made reference earlier to That's not correct, is it? That <sup>23</sup> the fact, according to you, that warning would monograph makes no reference to occupational <sup>24</sup> have been required in the '70s. <sup>24</sup> exposure -- studies of occupational exposure to

Page 334 Page 336 1 <sup>1</sup> talc, does it? exposure. I've seen the back-and-forth 2 DR. THOMPSON: Object to form. 2 about the advantages and disadvantages of 3 3 various designs and whether occupational THE WITNESS: I would have to 4 4 -- I would have to go back and look if I exposure to asbestos is relevant to 5 -- if I'm incorrect about -- well, no, in 5 assessment of the studies regarding 6 6 talcum powder use exposure to whatever the sense that it covers both asbestos 7 7 the things are in talcum powder that and fibrous product, I would have to 8 8 stand by that because that's all I meant predispose to -- to ovarian cancer. 9 9 by the statement. It was -- it was talc I've seen all of that 10 fibers on a par with asbestos. 10 discussion. I don't think any of it 11 11 So that is correct. changes my views. 12 12 BY MR. HEGARTY: My views are, you know, 13 13 fundamentally based on what I conclude is Are you aware that with regard to <sup>14</sup> IARC's findings as it relates to asbestos and 14 the presence of asbestos and asbestiform 15 ovarian cancer that none of the studies they particles in talc and on the failure of 16 evaluated involved exposure to talcum powder? Johnson & Johnson to meet its regulatory 17 17 DR. THOMPSON: Object to form. obligations regarding uncertainty. 18 <sup>18</sup> BY MR. HEGARTY: THE WITNESS: Would you 19 19 Did you read the individual studies repeat that? 20 BY MR. HEGARTY: on asbestos exposure and ovarian cancer cited by 21 the IARC Monograph 100C? Q. Sure. 22 22 On asbestos exposure and ovarian A. I couldn't tell. 23 Are you aware that with regard to cancer? I'd have to go look and see which those Q. <sup>24</sup> IARC's findings as it relates to asbestos and <sup>24</sup> were. Page 335 Page 337 <sup>1</sup> ovarian cancer, particularly the studies they Do you recall looking at the <sup>2</sup> looked at, none of those studies involved exposure <sup>2</sup> monograph and pulling the studies that it cites <sup>3</sup> or alleged exposure to asbestos from talcum powder <sup>3</sup> and reading the actual studies themselves? <sup>4</sup> products? I did not pull underlying studies 5 <sup>5</sup> from -- from this IARC report. Whether there's DR. THOMPSON: Same objection. 6 THE WITNESS: I don't know <sup>6</sup> some overlap between studies that I reviewed in 7 that. I would have to go back and look. <sup>7</sup> detail and these I can't say without doing the 8 They may have looked at actual or crosswalk. 9 Are you aware of the concern with potential sources of asbestos. Q. <sup>10</sup> BY MR. HEGARTY: regard to the studies looking at asbestos exposure 11 And do you recall that the IARC's and ovarian cancer risk of misclassification <sup>12</sup> findings as it relates to asbestos and ovarian between peritoneal mesothelioma and ovarian cancer were based primarily on five cohorts --13 cancer? 14 five heavy occupational cohort studies --14 DR. THOMPSON: Object to form. 15 DR. THOMPSON: Objection. 15 THE WITNESS: I cannot recall 16 BY MR. HEGARTY: an extensive discussion that -- of 17 17 -- of workers exposed to raw Q. potential confounders between peritoneal asbestos --18 mesothelioma and ovarian cancer, and I 19 19 DR. THOMPSON: Objection. invite you to show me something if you BY MR. HEGARTY: 20 have something to show me. 21 21 Q. -- in their employment? I have trouble seeing why that 22 22 DR. THOMPSON: Objection. would change the overall views that have

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THE WITNESS: I have seen

discussions about occupational asbestos

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been expressed regarding from good

studies and large -- large organizational

Page 338 Page 340 1 conclusions that there is a substantial Did you read -- have you read all 2 <sup>2</sup> the associated documents in Johnson & Johnson increased risk as a result of talcum 3 <sup>3</sup> testimony with regard to the document referenced powder exposure perineally. in your paragraph 116? <sup>4</sup> BY MR. HEGARTY: A. As a doctor, do you understand I doubt I have. 6 <sup>6</sup> whether there's any difficulties in diagnosing Q. Is it your testimony that Johnson & <sup>7</sup> ovarian cancer from peritoneal mesothelioma? <sup>7</sup> Johnson intended to deceive by its testing and DR. THOMPSON: Object to form. publicity as it relates to asbestos testing? 9 9 THE WITNESS: As a -- as a DR. THOMPSON: Object to form. 10 10 THE WITNESS: As we've matter cellular pathology, I've never 11 11 considered the question. discussed previously, my testimony does 12 <sup>12</sup> BY MR. HEGARTY: not go to Johnson & Johnson's corporate 13 13 Q. You're not a pathologist, right? motive or intent. 14 14 BY MR. HEGARTY: 15 15 Q. If we look over at paragraph 121 of Do all test methods for asbestos in your report, on what documents do you rely for talcum powder products have limits of detection? your statement in paragraph 121 that "Johnson & 17 DR. THOMPSON: Object to form. 18 <sup>18</sup> Johnson manipulated asbestos testing"? THE WITNESS: All practical 19 I was -- I was concerned by the methods would. Conceptually, not <sup>20</sup> back-and-forth regarding what the sensitivity 20 necessarily. If you look at everything, <sup>21</sup> thresholds should be with -- with whatever FDA 21 in everything you presumably find it. 22 <sup>22</sup> regarded as the acceptable assay method. Fibers are fibers, and they are 23 So if we look, again, that 121 is as conceptually detectable. <sup>24</sup> it says in some paragraph and it derives from the <sup>24</sup> BY MR. HEGARTY: Page 339 Page 341 <sup>1</sup> paragraphs that precede it. Is there a test method that shows So if we go -- if we go back and that no detection means none? <sup>3</sup> review that, you see a proposed regulation in 1973 DR. THOMPSON: Object to form. <sup>4</sup> calling for an amphibole 99.9 percent purity THE WITNESS: Is there a test <sup>5</sup> standard and 99.99 for chrysotile and using method that means none detected means <sup>6</sup> polarized microscopy, and then correspondence none? In this context? <sup>7</sup> subsequently involving Johnson & Johnson and FDA <sup>7</sup> BY MR. HEGARTY: <sup>8</sup> and the Personal Care Products Council, which Q. Correct. <sup>9</sup> including the statement in paragraph 116. Α. There should be test methods that "We believe it is critical for the" can be applied to small samples that will say that none detected in the sample means none in the 11 then predecessor -- the predecessor organization 12 "to now recommend these methods to the FDA before sample, but we're always in a sampling situation. 13 the art advances to more sophisticated techniques So, yes, there will always be <sup>14</sup> with higher levels of sensitization." choices in terms of sensitivity and detection 15 Which I think a fair reading of that limits as a practical matter. <sup>16</sup> is that Johnson & Johnson prefers to have no 16 So you acknowledge that with regard asbestos detectable in its products. to any testing method that humans are capable of 18 here in 2021, there will be limits of detection, And certainly if one combines that <sup>19</sup> even with the current website, which I have to say 19 correct? <sup>20</sup> really does concern me, these statements about 20 DR. THOMPSON: Object to form. <sup>21</sup> purity and the absence of contamination, I think 21 THE WITNESS: I think there <sup>22</sup> there is a historical story here that is a -- I 22 are different forms of limits, and here

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23 think it would be fair to characterize it as

<sup>24</sup> woeful ignorance.

-- here this ties back for me to -- to

disclosures of uncertainties as well as

Page 344 1 1 to disclosures of -- of known risks. In matter Johnson & Johnson has never 2 2 the -- in the sense that there's no accounted for that in the ways that the 3 3 suggestion, for example, on the Johnson & regulation requires. 4 Johnson website that other than, you <sup>4</sup> BY MR. HEGARTY: 5 know, one lot that in Johnson & Johnson's You already told us that you don't 6 <sup>6</sup> know the testing methods that Johnson & Johnson retelling was mistakenly characterized as 7 containing asbestos by FDA's contract <sup>7</sup> has used over the last 50 years to test its talc 8 labs, that there could ever be asbestos for the presence of asbestos, correct? 9 I know the correspondence regarding in Johnson & Johnson's talc. 10 <sup>10</sup> J4-1, regarding some of these other thresholds, I I think that is, in some ways, 11 <sup>11</sup> know are fairly significant; and these paragraphs Johnson & Johnson is the one asserting 12 the position you're ascribing to me in <sup>12</sup> documented disagreement between the company's 13 position on sensitivity and the FDA's proposed that question. They're the ones who are 14 <sup>14</sup> rule. A lot of harm can be caused by the claiming that there are no -- there are 15 differences between those testing standards. no limits. That, in fact, they can 16 simply say there is nothing because we 16 Not my question. 17 17 didn't find it in the way we looked. My question is: Do you agree that 18 you don't know what testing methods that Johnson & BY MR. HEGARTY: 19 Johnson used over the last 50 years to test its Do you have an opinion as to what 20 talcum powder products for the presence of testing methods of talc for asbestos are 21 asbestos -acceptable to substantiate the safety of the 22 product as it relates to asbestos? DR. THOMPSON: Object to form. 23 DR. THOMPSON: Object to form. <sup>23</sup> BY MR. HEGARTY: 24 THE WITNESS: Again, that's O. -- correct? Page 343 Page 345 1 I could not map for you detection not the -- that's not an expert opinion 2 <sup>2</sup> methods used by Johnson & Johnson in each decade that I'm giving. 3 That said, I've seen the <sup>3</sup> over the last 50 years. 4 descriptions of the last couple of years And it's not your testimony in this 5 of sort of FDA efforts to improve case as far as what testing methods must be done 6 as it relates to asbestos, looking for asbestos in asbestos detection, and I don't think any 7 <sup>7</sup> talc, to substantiate the safety of that product of that has resulted in a definitive 8 statement, but perhaps one is as it relates to asbestos, correct? 9 9 DR. THOMPSON: Object to form. forthcoming. 10 <sup>10</sup> BY MR. HEGARTY: THE WITNESS: So the -- so, 11 11 If you don't have an opinion as to again, forgive me. I'm really not trying 12 <sup>12</sup> what testing method is appropriate to substantiate to be argumentative here. 13 that there's no asbestos in talcum powder Substantiation for safety is 14 products, how do you know that that method is not not a matter of detectable asbestos. <sup>15</sup> being used today? 15 Substantiation for safety is: 16 16 DR. THOMPSON: Object to form. Does perineal use of baby powder -- of

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THE WITNESS: I have an opinion that over the relevant timeline history of when the women plaintiffs counsel represents have been exposed to Johnson's Baby Powder, the testing methods used were insufficient to rule out levels of asbestos that could cause carcinogenesis, and that as a regulatory

And that is a health hazard, which, if that has not been proven to be a zero risk or perhaps such a small risk that we could not consider it clinically significant, in that case, at a minimum,

talc containing baby powder products

ovarian cancer?

increase a woman's chance of contracting

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disclosure of nonsubstantiation for safety has to be made under the regulation.

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I don't want to get -- I mean, the presence of asbestos to me is compelling. The presence of asbestiform talc is compelling.

Those components, in my expert opinion, place regulatory obligations of disclosure and warning and instruction, some type of mitigation effort by the company, but some sort of mitigation obligation on the company, which I don't think the company has ever complied with or even seriously attempted to consider and -- but those are independent of this 740.10 obligation regarding uncertainty.

And every time there's a new study, every time there's a new report, every time there's a regulatory finding by a non-U.S. regulator, all of this in the paragraph that you asked me about a few minutes ago constitutes new information, of which the company is

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circumstances, it is Johnson & Johnson's obligation to have done a whole lot more

study to this than they apparently have,

and that would be my testimony.

#### BY MR. HEGARTY:

Q. But your -- and that testimony is,

according to your standard, as of 2021, to meet

the obligations under your interpretation of the

cosmetic regulations, Johnson & Johnson must prove

a negative, that talcum powder is incapable of

causing ovarian cancer, correct?

DR. THOMPSON: Object to form. THE WITNESS: No, I did not

say that.

## 15 BY MR. HEGARTY:

Q. So it's not your testimony that

17 Johnson & Johnson's obligation of the regulation

18 is to prove that talcum powder use cannot cause

19 ovarian cancer, correct?

20 DR THOMPSON: Object to form

DR. THOMPSON: Object to form.
THE WITNESS: Johnson &
Johnson's obligation under 740.10 is
either to prove that use of talcum powder
products does not cause ovarian cancer,

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Page 349

legally obligated to take account.

#### <sup>2</sup> BY MR. HEGARTY:

Q. Under your standard, it's Johnson &
 Johnson's obligation to prove that talcum powder
 use does not cause ovarian cancer, correct?

MS. PARFITT: Objection.

Form.

DR. THOMPSON: Object to form.

THE WITNESS: If there were no studies suggesting that it did and no reason to think that it would, it's not in my reading of cosmetic self-regulation incumbent to specifically disprove every conceivable harm.

The obligation is to substantiate safety for the product as labeled and as reasonably and customarily used. It's the same as the warning standard, in essence.

But in light of 1970s to today, roughly 40 years of sustained scientific interest in and controversy regarding ovarian cancer risk from perineal talcum powder, yes, under those

which today in 2021 it will be unable to 2 do, or to put in place, as it should have 3 for many, many years, the required 4 disclosure of "safety not determined," or 5 as it has done for whatever reason it 6 asserts to reformulate the product so 7 it's not sold to the United States or 8 Canada. And I wish it weren't sold 9 anywhere in the world.

# 10 BY MR. HEGARTY:

Q. But you would agree, at least on your medical background, as it relates to exposure and disease, it's impossible for anybody to prove a negative, correct?

DR. THOMPSON: Objection.

Form.

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THE WITNESS: I can't really answer that question.

There are negatives that can be proved to high degrees of statistical probability. In the sense of conditions that are extremely evident that have no other causes, you know, there are ways to prove a negative. Page 350

When there is, you know, a condition that is multifactorial, when there is a condition that has latency, there's conditions that suit a lot of -- a lot of cancer development, then, yes, it would be very, very hard to prove a negative.

And yet even there, we have epidemiological studies all the time that are done and, frankly, you know, drug and device studies that are done -- well, drug studies that are done all the time that in essence demonstrate to a level of statistical certainty that there's no increased risk.

# <sup>16</sup> BY MR. HEGARTY:

- Q. You comment in this part of your report beginning at page 19 about CIR; is that correct?
- <sup>20</sup> A. Yes.

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- Q. Are you an expert on the process by which CIR reviews cosmetic ingredients?
- A. I've read a fair amount about it in connection with this case.

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Q. Have you ever reviewed anything
 about the CIR and its processes before being
 contacted by plaintiffs' counsel in this case?

<sup>4</sup> A. No. I find it very interesting,

<sup>5</sup> though.

- <sup>6</sup> Q. Have you ever been involved in a CIR <sup>7</sup> review?
- <sup>8</sup> A. No.
- <sup>9</sup> Q. Have you ever studied a CIR review
- <sup>10</sup> besides its review for talcum powder products?
- A. In connection with this case and
- 12 reviewing cosmetics law and regulation and
- <sup>13</sup> self-regulatory processes, yes, I have read about
- <sup>14</sup> other CIR processes. And that 1998 internal
- 15 study -- FDA study that we've discussed, and that
- <sup>16</sup> you made a copy of, has a fairly extensive
- discussion of both the advantages and the profound
- <sup>18</sup> disadvantages and questions around CIR.
- Q. Have you discussed with anyone at
- <sup>20</sup> CIR how it reviews cosmetic ingredient petitions?
- <sup>21</sup> A. No.
- Q. Do you know who Alan Anderson is?
- <sup>23</sup> A. No.

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Q. Do you know -- you have his

<sup>1</sup> testimony referenced in your materials.

Did you read his testimony?

A. If we can point me to it, I might

<sup>4</sup> remember. I don't -- I don't -- just so you know,

<sup>5</sup> I remember things by substance generally, not by <sup>6</sup> title.

Q. He was the head of the CIR during the time it reviewed talc.

Do you recall that?

A. I do recall reading -- reading some
 testimony about -- about the CIR -- the specifics
 of the CIR talc review. I don't recall reading
 his testimony.

<sup>14</sup> Q. Are you aware that he testified that <sup>15</sup> the CIR properly reviewed talc?

<sup>16</sup> A. I'm not aware of that. It wouldn't <sup>17</sup> surprise me.

<sup>18</sup> Q. Are you aware he testified that the <sup>19</sup> CIR review was independent of any industry or <sup>20</sup> other group?

DR. THOMPSON: Object to form.
THE WITNESS: Again, I don't
think I read his testimony, or at least I
can't recall it right now. The

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Page 352

particular information you're sharing is

not specific.

## <sup>3</sup> BY MR. HEGARTY:

Q. Do you recall -- so you didn't read
 his testimony that he said -- where he said that
 CIR does not favor industry?

DR. THOMPSON: Object to form.

THE WITNESS: No, but there is other evidence that CIR has both

perceived and actual conflicts of
 interest

interest.

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#### BY MR. HEGARTY:

Q. Are you aware that he prepared an expert report?

DR. THOMPSON: Object to form. THE WITNESS: No, I'm not.

#### <sup>17</sup> BY MR. HEGARTY:

<sup>18</sup> Q. Have you reviewed his expert report <sup>19</sup> in this litigation?

DR. THOMPSON: Object to form.
THE WITNESS: No, but I'd be

very happy to.
BY MR. HEGARTY:

Q. Would that be something you'd be

Page 354 Page 356 <sup>1</sup> interested in seeing? I also did a little independent 2 Very much. <sup>2</sup> investigation to see where Citizen's Petitions A. 3 Because you do comment on the CIR in <sup>3</sup> were available online within the FDA, and they your report, correct? <sup>4</sup> were not available. I think they were available A. Yes. <sup>5</sup> in the device area. Though I can't exactly recall 6 <sup>6</sup> now because I didn't take notes on that. But Q. Don't you think it would be <sup>7</sup> appropriate to read the testimony and the expert <sup>7</sup> there were none -- there was not data available report of the person who was overseeing the CIR currently on the cosmetics side. when it looked at talcum powder? Do you cite the authorities you just 10 MS. PARFITT: Object to form. 10 provided in your answer in your expert report? 11 DR. THOMPSON: Object to form. 11 The peer-review article is -- is 12 12 cited right -- right here in the paragraph above THE WITNESS: I would be 13 <sup>13</sup> the one that you cited, which was this Chen et al. delighted to look at any information your 14 petitioning the FDA. client would like to offer that bears on 15 15 The GAO or IG report is not cited in my opinions. <sup>16</sup> BY MR. HEGARTY: 16 the -- in the report but -- in my report, I don't 17 Have you asked plaintiffs' counsel <sup>17</sup> believe, but was made available to me after it was for any testimony from -- from individuals about submitted, and I think has been shared with and the CIR process? disclosed to you. 20 DR. THOMPSON: Object to form. 20 That's not referenced in your 21 <sup>21</sup> report, is it? THE WITNESS: I asked 22 22 That particular, the G -- I think -plaintiffs' counsel for documentation 23 we'll call it the GAO report for lack of having to regarding the origins and early history 24 <sup>24</sup> say both each time. It's not referenced in the and general continuing activities of CIR. Page 355 Page 357 1 <sup>1</sup> report, but it confirmed what I had learned about It didn't occur to me to ask 2 the Citizen's Petition process elsewhere. about current CIR operations testimony. 3 If I had known that was available, I If you turn over to page -- to 0. certainly would have asked for it. paragraph 162 of your report. Α. <sup>5</sup> BY MR. HEGARTY: Yes. If you look over at page 143 of your 6 Q. There you refer to FDA Congressional <sup>7</sup> -- I'm sorry -- paragraph 143 of your report. activity --A. Uh-huh. A. 9 9 What is your authority for the Q. Q. -- concerning the safety of cosmetic statement you make in that paragraph? 10 products? 11 In other words, where did you get A. Yes. 12 12 that information from? 0. And there you detail -- in the So there's a peer-review article on <sup>13</sup> section detail hearings that the House <sup>14</sup> Citizen Petition processes, which is cited in the <sup>14</sup> subcommittee had in 2019 regarding the safety of <sup>15</sup> report, which -- which I read. I think that -- I <sup>15</sup> cosmetic products? <sup>16</sup> think the information either came directly out of 16 A. Yes. 17 <sup>17</sup> that or was -- or was my back-of-the-envelope O. Did you read the transcripts or <sup>18</sup> calculation from what I was seeing in that watch the video of those hearings? <sup>19</sup> article. 19 I -- I read all the transcripts at There's also either a -- either a <sup>20</sup> different levels of detail. There were a lot. <sup>21</sup> There were, I think, several days of testimony. <sup>21</sup> GAO or an Inspector General report on the <sup>22</sup> Citizen's Petition process that's about 20 years <sup>22</sup> Some I was able to read more thoroughly than <sup>23</sup> old, but it sheds a lot of light on the delays <sup>23</sup> others, but I reviewed all -- all the people <sup>24</sup> involved with the Citizen's Petition. <sup>24</sup> testifying in each day of hearings.

Page 358 Page 360 1 1 Are you aware that plaintiffs' to me, nor would it have mattered to my <sup>2</sup> experts testified before that House subcommittee? 2 interpretation of the testimony, to know 3 I think at the time I reviewed those about people being disinterested in the 4 <sup>4</sup> transcripts, I wasn't aware of who might have been sense that in a properly convened <sup>5</sup> a plaintiffs' expert; but I think in reading some Congressional hearing everyone is 6 <sup>6</sup> of the transcripts, it became apparent that at interested. <sup>7</sup> least a couple of them were. <sup>7</sup> BY MR. HEGARTY: Do you know who Ann McTiernan is? Is it your contention that I read it at the time. I don't Congressional hearings are motivated by --A. 10 Congressional hearings like this are motivated recall now. 11 because of safety concerns in every instance? Are you aware that plaintiffs' <sup>12</sup> lawyers paid her way to attend that subcommittee 12 DR. THOMPSON: Object to form. 13 hearing? THE WITNESS: Congressional 14 14 hearings are motivated by many things, DR. THOMPSON: Object to form. 15 15 THE WITNESS: I am now aware but safety concerns are one of the many 16 16 of that. things that elected representatives 17 17 BY MR. HEGARTY: receive political benefits from 18 18 Are you aware that -- that she addressing. checked with plaintiffs' lawyers before agreeing BY MR. HEGARTY: to testify at that hearing? 20 They can also be motivated by 21 21 DR. THOMPSON: Object to form. political concerns, correct? 22 22 MS. PARFITT: Object to form. I would resist the characterization 23 THE WITNESS: I did not know of political because it's, I think, in my view, 24 that. Again, really all I know about the <sup>24</sup> it's a much overused term that we really can't Page 361 Page 359 <sup>1</sup> explain or even define these days. testimony is the testimony. So, again, I don't know if I want to BY MR. HEGARTY: 3 Is it your position that -- let me <sup>3</sup> -- to try to lecture in this -- in this forum on <sup>4</sup> look at that. Strike that. <sup>4</sup> what I know about -- about designing Congressional <sup>5</sup> hearings. Again --Α. 6 But in general, the committee chair Q. Would you consider Dr. McTiernan to <sup>7</sup> be an uninterested or disinterested scientist? <sup>7</sup> or subcommittee chair that controls the chamber DR. THOMPSON: Object to form. <sup>8</sup> controls the hearings and then takes, insofar as 9 <sup>9</sup> that person takes input from within her own party THE WITNESS: Thank you. 10 <sup>10</sup> or across the aisle, different people come to Thank you for using those words 11 <sup>11</sup> testify. Different committees, different correctly. I do appreciate it. 12 I don't have an opinion on <sup>12</sup> subcommittees have different levels of 13 that. When I was reading the hearing <sup>13</sup> bipartisanship, different levels of comity, and 14 <sup>14</sup> different hearings as a result. testimony -- as I'm sure you know, 15 15 Congressional hearings are planned and Is it your testimony that there were 16 orchestrated and, hopefully, useful and <sup>16</sup> no political motivations behind the hearing you 17 reference in your report? testimony is expert and accurate. 18 18 Those hearings, as I recall, DR. THOMPSON: Object to form. 19 19 THE WITNESS: I don't know were a combination of sort of expert 20 testimony and layperson testimony of the 20 what you mean by "political motivations." 21 21 BY MR. HEGARTY: sort of compelling anecdote variety that 22 22 is highly representative of Congressional Are you --23 23 I'm not being naive. I really don't hearings. 24 <sup>24</sup> know what you mean by "political motivations." So it would not have occurred

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- 1 Really? You don't know what Q. political motivations are?
- In this instance, a partisan <sup>4</sup> motivation? A particular electoral outcome? I don't know. What might you mean?
  - Well, all of the above. Q.

7 Do you know whether any of those considerations went into the hearings?

In these instances --

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DR. THOMPSON: Object to form.

THE WITNESS: In these instances, I have to say, I'm very much struck by the fact that there has been this Feinstein -- Feinstein-Collins proposal for now I think close to more than five, perhaps closer to 10 years in some form.

There is bipartisan support that, you know, the Trump's administration FDA was quite clear on the need for additional cosmetic regulation and, for that matter, it appears that Johnson & Johnson is supportive.

And I think my -- my struggle

<sup>1</sup> Dr. Longo whose report you cited spoke at that <sup>2</sup> hearing?

I don't recall that, but I read the <sup>4</sup> names of all of the participants as I read the <sup>5</sup> hearing transcripts. So I presumably was aware of <sup>6</sup> it at the time.

Q. You made mention just a moment ago to legislation introduced by Senator Feinstein.

And have you read the press releases she issued with regard to that legislation?

I actually focused on reading the 12 text of the bill.

13 And the text of the bill does not refer to talcum powder products, does it? 15

The text of the bill does not. It's <sup>16</sup> a -- it's a very interesting bill with a lot of provisions that I find attractive and with some provisions that I find rather cryptic that reflect the attempt to secure bipartisanship.

Did you read -- so you did not read <sup>21</sup> with regard to her press release that <sup>22</sup> organizations that support the Act include Johnson <sup>23</sup> & Johnson?

> A. Oh, I did read that part if that was

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-- my struggle answering these particular questions is best captured by taking us back to the bolded language that precedes the paragraphs that we're discussing, which is just the "Cosmetics regulation may be on the verge of significant reform and improvement because of unprevented harm to consumers" and I say "whether or not manufacturers cooperate."

It doesn't mean manufacturers won't cooperate. It just means that it appears to be a political moment where something might happen to finally improve cosmetics regulations and the funds that support it.

## <sup>16</sup> BY MR. HEGARTY:

17 If you look at paragraph 165 of your report, you again refer to a hearing on March 12, <sup>19</sup> 2019, and then other hearings that followed in <sup>20</sup> 2019.

Do you see that?

- 22 A. Yes.
- 23 Q. Are you aware that at those
- <sup>24</sup> hearings, at least the December 2019 hearing, that

- <sup>1</sup> the press release. Yes, because I had mentioned <sup>2</sup> that to you earlier that I had seen some mention <sup>3</sup> that Johnson & Johnson was supportive. I said <sup>4</sup> that several hours ago.
- Did you make reference to that support anywhere in your report?

DR. THOMPSON: Object to form. THE WITNESS: I actually did

not have the text of the most recent bill at the time that I submitted the report. It was something I wanted to make sure I

was keeping track of as my expert service continues.

#### 14 BY MR. HEGARTY:

- 15 If you look at paragraph 171 of your 16 report, please.
  - A. Sure.
- 18 O. You make reference there to 19 O'Shaughnessy and Wille deposition. 20

Who is O'Shaughnessy?

21 I have forgotten who O'Shaughnessy <sup>22</sup> is. Wille was the deposition over a number of days that outlined Johnson & Johnson's regulatory <sup>24</sup> posture with respect to these products. It was a

Page 366 Page 368 1 <sup>1</sup> difficult transcript to read. that's a badly written sentence. 2 What testimony from them are you So I -- I can't interpret <sup>3</sup> relying on for purposes of any of your statements 3 exactly what the "respond to" words mean, 4 <sup>4</sup> in this paragraph? but it -- it did not engage in the type DR. THOMPSON: Object to form. 5 of responsible corporate behavior in a 6 6 THE WITNESS: So I point out voluntary system that I would like to see 7 7 that this is a summary of opinions a company do when it has as much 8 8 paragraph that also includes subsumed all experience with event reporting and assay 9 9 of the prior -- the prior paragraphs and ingredient reporting as Johnson & 10 10 and -- and their references. Johnson does in its other lines of 11 11 So, you know, in this case, business. 12 this has -- this focuses primarily on <sup>12</sup> BY MR. HEGARTY: 13 your -- your client's apparent 13 We've already established, I 14 uninterest, extensively discussed in the <sup>14</sup> think -- and you tell me if I'm wrong -- that 15 you've never published in the -- in the publicly Wille transcript, in supporting more 16 detailed or definitive studies over the available literature the standards for what it 17 decades. <sup>17</sup> takes to be a responsible company as it relates to <sup>18</sup> BY MR. HEGARTY: a cosmetic, correct? 19 19 What do you rely upon from A. Correct. <sup>20</sup> Mr. O'Shaughnessy's transcripts for purposes of 20 You've never lectured on what is O. <sup>21</sup> this paragraph? <sup>21</sup> responsible corporate behavior with regard to a 22 A. I can't recall. cosmetic, correct? 23 23 Did you read the entirety of his With regard to a cosmetic, correct. O. <sup>24</sup> deposition transcript? 24 Q. You've never lectured or taught Page 367 Page 369 I don't believe I read the entirety. <sup>1</sup> courses on the responsible corporate behavior of a <sup>2</sup> I do believe I saw it. manufacturer of a cosmetic, correct? Did you read the entirety of 3 A. A cosmetic, correct. <sup>4</sup> Ms. Wille's transcript? And prior to being contacted by plaintiffs' counsel in this case, you would not A. Yes. Q. Are you aware that both testified --<sup>6</sup> have called yourself an expert on what is the <sup>7</sup> Mr. O'Shaughnessy and Ms. Wille -- that -- Dr. <sup>7</sup> responsible corporate behavior of a manufacturer <sup>8</sup> Wille -- that there's never been asbestos in of a cosmetic, correct? 9 <sup>9</sup> Johnson & Johnson's talcum powder products? DR. THOMPSON: Object to form. 10 10 Do you recall that testimony? THE WITNESS: I don't -- I 11 11 don't serve as an expert in litigation Again, it was a challenging 12 <sup>12</sup> transcript to distill to draw clear conclusions very often, as we've discussed. This is 13 <sup>13</sup> from, but I mainly recall Dr. Wille for all of the first time in, roughly, a decade. 14 <sup>14</sup> these relying herself on other conclusions by I would consider myself an <sup>15</sup> other Johnson & Johnson employees and 15 expert on responsible corporate behavior 16 <sup>16</sup> representatives. with respect to health and safety 17 There was very little, as I recall, generally. <sup>18</sup> in that very long transcript that -- that really BY MR. HEGARTY: <sup>19</sup> was a matter of her personal knowledge. 19 You have never before this case If you look at paragraph 172 of your analyzed the -- what you consider to be the <sup>21</sup> report, what did Johnson & Johnson not respond to corporate behavior of a manufacturer of a cosmetic <sup>22</sup> with regard to FDA? product, correct? 23 23 DR. THOMPSON: Object to form. DR. THOMPSON: Object to form. 24 24 THE WITNESS: That's --THE WITNESS: Correct.

Page 370 Page 372 <sup>1</sup> BY MR. HEGARTY: <sup>1</sup> BY MR. HEGARTY: I'll be jumping around a little bit And never analyzed before being <sup>3</sup> hired in this case with regard to what is a <sup>3</sup> because I went back over. Probably just hit <sup>4</sup> responsible -- what is responsible corporate <sup>4</sup> things here or there that may not be a <sup>5</sup> behavior compliance with the cosmetic regulations, <sup>5</sup> concentrated set of questions about any subject area. 6 correct? 7 DR. THOMPSON: Object to form. 7 A. Okay. 8 8 THE WITNESS: I've never MR. HEGARTY: We talked 9 9 earlier about whether you had contact analyzed -- I've never compared a 10 corporation's conduct to the requirements 10 with any and communicated with any of the 11 11 of the cosmetic regulations before expert of plaintiffs in this case, and 12 12 I'm going to mark as Exhibit 19 a list of becoming involved in this matter. 13 13 BY MR. HEGARTY: the plaintiffs' experts that have been 14 14 disclosed in these cases. If we look at paragraph 175, you say 15 "Johnson & Johnson did not register its cosmetics (Document marked for accurately." 16 identification as Sage Exhibit 19.) 17 17 BY MR. HEGARTY: Where did Johnson & Johnson not register its cosmetics? 18 18 Would you look at that list and tell 19 The registration requirements are me whether you know any of those names. I should <sup>20</sup> voluntary under the existing scheme and, you know, say, know any of them personally. <sup>21</sup> its registration of facilities, but then its 21 (Reviews document.) <sup>22</sup> products and ingredients that are associated with 22 I don't know any of them personally. 23 each facility. Okay. In talking about your 24 Something that's very interesting is <sup>24</sup> methodology for your review of material, what was Page 373 Page 371 <sup>1</sup> under the proposed legislation, the <sup>1</sup> your method yourself for ensuring that you had the pertinent information that you needed to come to <sup>2</sup> Feinstein-Collins bill, not only would <sup>3</sup> registration be mandatory, but it would be an <sup>3</sup> conclusions or opinions in this litigation? <sup>4</sup> explicit certification in the process of In other words, what method did you <sup>5</sup> registering a facility for safety of every product apply to -- to ensure that you had the information <sup>6</sup> and ingredient has been substantiated or that that you needed to provide opinions in your report? <sup>7</sup> warning we've long described discussed has been Yeah. I applied the same method I <sup>8</sup> given. So there's a clear understanding that would be applying if I were writing an article. <sup>9</sup> there's a relationship between registering one's <sup>9</sup> The same method I would be applying if I were <sup>10</sup> facilities and substantiating the safety of one's 10 planning a series of classes on a topic. Identify the questions in a products and ingredients. 12 This, again, these are -- these are <sup>12</sup> regulatory context. Go to the regulatory sources. <sup>13</sup> conclusions that summarize and distill a lot of Look at commentary that might be out there. <sup>14</sup> the prior contents of -- of my report, and the <sup>14</sup> Things that are very relevant to me are historical <sup>15</sup> notion of registering its cosmetics accurately is, context, political context, economic context, <sup>16</sup> in my expert opinion, as we discussed very close 16 industrial context. to the beginning of today, the ingredients listed Here there was a heavy overlay of -are not the full contents of these products. <sup>18</sup> of scientific research and epidemiology. So I had 19 19 to sort of identify each of those areas and MR. HEGARTY: Let's take a 20 satisfy myself that I had asked the questions and break. Let's go off the record. 21 (Recess: 4:01 p.m. -<sup>21</sup> found the material that would -- that would 22 22 provide the information I needed. 4:28 p.m.) 23 23 MR. HEGARTY: All right. Have you ever published that 24 We're back on the record, Dr. Sage. <sup>24</sup> methodology in any article or any document?

Page 376 1 DR. THOMPSON: Object to form. <sup>1</sup> the FDA letter. 2 THE WITNESS: I have not I believe it's right here. I can 3 published it. One could infer it from a grab it from the one you gave me. 4 If you look at the first page of lot of my work. I have a -- particularly 5 in my longer work, I have a voice and a <sup>5</sup> that exhibit, Exhibit No. 7, you see the third 6 <sup>6</sup> line it refers to: "Year 1994 petition requested style that is fairly recognizable among 7 my peer group. <sup>7</sup> all cosmetic talc bear labels with a warning such <sup>8</sup> BY MR. HEGARTY: as" and then lists the warning, correct? Can you cite for me anyone who has A. Yes. 10 10 come to the same opinions as you set out in your Then if you look a few lines down, O. <sup>11</sup> it says: "Additionally, year 2008 petition expert report? 12 DR. THOMPSON: Object to form. requested that cosmetic talcum powder products 13 <sup>13</sup> bear labels with a prominent warning such as" and THE WITNESS: I can't cite 14 then it lists another suggested warning, correct? anyone who's come to those opinions in 15 15 this matter. Α. Yes. 16 <sup>16</sup> BY MR. HEGARTY: O. So is it your contention that even 17 <sup>17</sup> with that "such as" language that FDA would only And when I'm talking about anyone, <sup>18</sup> I'm talking about in the litigation or outside the or only based its conclusions with regard to this <sup>19</sup> litigation. letter as to the two samples of warnings in that 20 first paragraph? Can you cite for me anyone that <sup>21</sup> you're aware of who's come to the same opinions 21 DR. THOMPSON: Object to form. 22 <sup>22</sup> that you have that you set out in your expert THE WITNESS: I think the 23 <sup>23</sup> report? "such as" is the writer of this letter's 24 DR. THOMPSON: Object to form. 24 not fully clear way of expressing in all Page 375 Page 377 THE WITNESS: I can't cite material respects "equivalent to." So 2 2 anyone who has come to the opinions I that a word or two might vary, but the 3 3 have regarding this situation and these thrust of it was identical. 4 4 obligations. I don't think that this 5 <sup>5</sup> BY MR. HEGARTY: paragraph implies that the FDA is By citing it in your report, you 6 declining a request to pursue a warning 7 <sup>7</sup> certainly agree that FDA's April 2014 letter is of any kind. I think this is quite relevant to the issues that you analyzed in this 8 specific to these -- to the requested 9 case, correct? language, and that is my understanding of 10 10 MS. PARFITT: Objection. the Citizen's Petition process. 11 11 Form. BY MR. HEGARTY: 12 12 THE WITNESS: It is relevant. That was what I was going to ask O. 13 you. 13 It is not directly relevant to 14 14 manufacturer's obligations to warn nor is What do you base that opinion on 15 it directly relevant to manufacturer's <sup>15</sup> that in particular that FDA was not saying in this 16 obligations to disclose a <sup>16</sup> letter that it's not -- that it doesn't believe 17 any type of warning would be appropriate? nonsubstantiation of safety. 18 18 It is certainly relevant to Because the position process, which, 19 19 as we've discussed, has delays, gaps, and flaws the relationship between the FDA and the 20 other parties who might be involved in <sup>20</sup> that are well-recognized and that are immediately 21 <sup>21</sup> evident in the letter that says "Your petitions approving the safety of cosmetics. 22 BY MR. HEGARTY: <sup>22</sup> dated 1994 and 2008 are being addressed in 2014." Do you have that exhibit? It's <sup>23</sup> That already tells you something, you know, about <sup>24</sup> Exhibit No. 7, or you can look in your notebook to <sup>24</sup> the Citizen's Petition process is, to put it

5-8e, Films, 08/23/24 Page 97 of 110 Page 378 Page <sup>1</sup> politely, suboptimal. Had you ever reviewed any <sup>2</sup> documents -- internal documents prior to being The Citizen's Petition process is <sup>3</sup> designed to make specific requests of FDA. It's <sup>3</sup> contacted to serve as an expert witness in this <sup>4</sup> not a generic request to do something about a case from PCPC or CTFA? <sup>5</sup> potential problem, and so the response to the A. No. <sup>6</sup> Citizen's Petition is exactly that. It is either Q. Had you ever heard of PCPC or CTFA <sup>7</sup> agreeing or declining to do the action that's prior to being contacted by plaintiffs' counsel in <sup>8</sup> requested. this case? 9 Q. Your authority for that is what? A. In passing, probably, but I haven't 10 What I understand from the text of made a mental note of it. Trade groups, <sup>11</sup> the regulations, what I've seen in Citizen's particularly trade groups involving health-related <sup>12</sup> Petitions, and what I've read about the Citizen's consumer products, would be within what I would <sup>13</sup> Petitions process including that, again, we're read. <sup>14</sup> just calling it the GAO report. 14 Q. Is there such a mineral as 15 And prior to being hired to serve as asbestos-free talc --<sup>16</sup> an expert witness in this case, you had never seen 16 DR. THOMPSON: Object to form. <sup>17</sup> any company documents of Johnson & Johnson, 17 BY MR. HEGARTY: <sup>18</sup> correct? 18 -- in your opinion? 19 19 I certainly had seen no proprietary DR. THOMPSON: Object to form. company documents of Johnson & Johnson. I'm sure 20 THE WITNESS: I don't have a <sup>21</sup> I had seen various documents of Johnson & Johnson 21 scientific basis for giving an opinion on 22 in, say, the drug and device domain in passing. that. I have seen nothing in this matter 23 23 Do you know who Imerys is? to persuade me that -- that the majority 24 24 or anything approximating all of talc Α. Yes. Page 381 Page 379 Have you seen any documents by products are truly asbestos-free. BY MR. HEGARTY: <sup>2</sup> Imerys prior to being hired to serve as an expert 3 in this case? 3 Do you have an opinion one way or O. A.

5 Had you done any work prior to being O. <sup>6</sup> hired in this case for any type of mining company?

A.

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8 Q. Do you have any expertise with <sup>9</sup> regard to the obligations of a mining company as 10 it relates to talcum powder products?

With respect to --

12 DR. THOMPSON: Object to form. 13 THE WITNESS: -- talcum powder 14 products, no. In my legal practice days, 15 I wrote the brief in Supreme Court 16 litigation involving OSHA obligations, 17 which also touched on mine safety 18 obligations, and so I have some passing

#### 20 BY MR. HEGARTY:

21 Prior to being contacted to serve as <sup>22</sup> an expert witness in this case, had you had any dealings with PCPC, also known as CTFA? 24 A. No.

acquaintance with mining safety.

<sup>4</sup> the other whether you can mine talc that's asbestos-free?

A. I have no --DR. THOMPSON: Object to form. THE WITNESS: I have no opinion on that. I have seen assertions of that and I have seen contrary

11 positions.

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## <sup>12</sup> BY MR. HEGARTY:

13 Do you have an opinion as to the amount of exposure -- the minimum amount of exposure to asbestos that can cause ovarian 16 cancer?

17 I have relied, as we've discussed, on positions and determinations by others that there is no safe level of asbestos exposure, and insofar as there are paths by which asbestos can <sup>21</sup> reach the ovaries, I would apply that same zero <sup>22</sup> threshold to ovarian cancer.

So is it your opinion that a single <sup>24</sup> fiber of asbestos is capable of causing ovarian

Page 382 Page 384 1 <sup>1</sup> cancer? THE WITNESS: I would have --2 2 A. I have no reason to think otherwise. I would have to go and reread the Q. And with regard to the medical criteria for the classification, but I'll 4 <sup>4</sup> literature as it relates to migration of talc or accept that characterization. BY MR. HEGARTY: <sup>5</sup> asbestos fibers from perineal use of -- of talcum <sup>6</sup> powder products, have you done an analysis Let me go ahead and show you the <sup>7</sup> yourself of that medical literature? <sup>7</sup> Volume 93 Monograph 2010, and I've only got two I have read some of that literature, copies. I'm sorry. <sup>9</sup> and my -- my medical view, which is not the expert Oh, I have one if it's easier. Do A. you want --<sup>10</sup> view that I'm, you know, here presenting in terms 10 11 <sup>11</sup> of regulatory design and regulatory obligation, my MR. HEGARTY: You can give 12 that to Margaret. 12 medical -- my medical view is that there are 13 <sup>13</sup> demonstrated pathways by which perineal use of DR. THOMPSON: I have it. <sup>14</sup> talc can reach the ovary. 14 MR. HEGARTY: We'll leave it 15 15 And that's based on the medical there so I don't have to take it back. <sup>16</sup> literature you reference in your expert report, 16 You still have to mark it as an exhibit. 17 correct? THE WITNESS: There you go. 18 18 A. Yes. (Document marked for 19 O. And are you aware of any studies 19 identification as Sage Exhibit 20.) <sup>20</sup> that have showed that external application or 20 BY MR. HEGARTY: <sup>21</sup> perineal application of any powder or any particle 21 Q. And have you reviewed that <sup>22</sup> has migrated to the tubes and ovaries, in other 22 monograph? 23 <sup>23</sup> words, where it's been tracked from external A. 24 <sup>24</sup> application to the tubes and ovaries? Q. And if you look at page 31 of that Page 383 Page 385 I would have to go back and review <sup>1</sup> monograph, at the very bottom, is it your <sup>2</sup> the studies to see if anything -- if any studies I <sup>2</sup> understanding that with regard to a 2B finding, <sup>3</sup> reviewed were designed to illustrate that exactly. <sup>3</sup> that's a finding of limited notice of And you have not done any -- any of <sup>4</sup> carcinogenicity? <sup>5</sup> your own analysis as to whether any bottle of A. I'm sorry. I'm looking for the <sup>6</sup> Johnson's Baby Powder or Shower to Shower actually correlation between the description and the -- and <sup>7</sup> has -- has ever had asbestos in it, correct? the classification of the category. A. My own analysis? No. Well, do you understand one way or Q. Going back to your expert report and Q. another? <sup>10</sup> we'll go back over a few paragraphs. But I'm -- but if -- so, yes. "A 11 Sure. positive association has been observed, but 12 Q. In paragraph 27, you make reference chance, bias, or confounding could not be ruled 13 to IARC's monograph with regard to -- IARC's out." Absolutely. 14 monograph in 2010 where it classified the perineal And I would -- and I would, again, 15 use of talc-based body powder (non-asbestiform) as point out that -- that a 2B finding alone -- and <sup>16</sup> Group 2B. 16 this is, you know, for platy talc -- would be 17 exactly the sort of information that's Do you see that reference? 18 contemplated by the regulation to support a A. In paragraph 28? 19 28. I'm sorry. Yes, 28. revisiting of substantiation and trigger a "safety 2.0 The 2B finding means that chance, not determined" notice. <sup>21</sup> bias, and confounding cannot be ruled out with 21 And I should have -- in what you reasonable certainty, correct? 22 pointed me to -- I'm sorry and I hope that's not a 23 MS. PARFITT: Objection to problem. 24 24 form. O. No, go ahead.

Page 386 Page 388 "A positive association has been <sup>1</sup> referenced in that article? <sup>2</sup> observed for which a causal interpretation is I can't -- I can't recall. Probably <sup>3</sup> considered by the working group to be credible," <sup>3</sup> not. <sup>4</sup> and then it goes with the limitation language that Q. Do you know whether certain forms of <sup>5</sup> you quoted. asbestos come in asbestos and non-asbestos forms? Q. Is it your opinion that a single A. I ---<sup>7</sup> epidemiologic study finding association between a 7 DR. THOMPSON: Object to form. cosmetic and an illness is enough to consider that THE WITNESS: I know that to 9 cosmetic not proved safe? be the case in some of the material that 10 DR. THOMPSON: Object to form. 10 I have reviewed in terms of how the 11 THE WITNESS: It would depend 11 fibers and crystals are structured. 12 on the study, but conceptually, yes. 12 BY MR. HEGARTY: 13 BY MR. HEGARTY: 13 If you look at paragraph 50 of your 14 <sup>14</sup> report, your footnote 15, you include footnote 15. Can you cite for me any published <sup>15</sup> You make a statement, though, in that paragraph 15 standard for assessing the safety of a cosmetic? 16 DR. THOMPSON: Object to form. that said: 17 17 THE WITNESS: I have seen CIR "Asbestos was known to cause lung 18 cancer since the 1930s and was suspected to cause material about their various 19 classifications. I have also seen Health ovarian cancer since the 1960s." 20 Canada report. I've also seen references And my question is: What do you 21 <sup>21</sup> cite as your authority for saying that asbestos to other types of safety standards in 22 many of the materials that we've <sup>22</sup> was suspected to cause ovarian cancer since the 23 <sup>23</sup> 1960s? discussed today.

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Q. Okay. Other than the CIR and Health
Canada, can you cite for me any published
standards on assessing the safety of a cosmetic?
A. No.
Q. If you look over at paragraph 47 of
your report -A. Yes.

<sup>24</sup> BY MR. HEGARTY:

<sup>8</sup> Q. -- you cite in footnote 10 a number <sup>9</sup> of studies.

Do you know whether any of those studies tested Johnson's Baby Powder?

 $^{12}$  A. I would have to go back and look. I  $^{13}$  do not know.

Oh, wait a second. In the -- in the "Blunt" or Blount reference here, the quote is then enhanced with confirmed that the tested -- the tested sample was, in fact, Johnson's Baby Powder.

<sup>19</sup> Q. As to Dr. Blount, did you read her <sup>20</sup> deposition in this litigation?

A. I -- I believe I received it.

Again, it's not one that I read in -- in full.

Q. Did you read what she had to say about the particular sample that she tested as

footnote 15, which is the 30(b)(6) deposition and
 exhibits of John Hopkins and Exhibit 28.

And, again, you refer only there to

A. So I'm right now looking at the appendix in my report that was the summary of scientific evidence to see if one of those pieces specifically supports that statement.

(Reviews document.)
 None of these of the published

<sup>9</sup> articles date to the 1960s, but the Henderson 1971

article talks about the possibility of an
 association of talc and asbestos and the

<sup>2</sup> possibility of relationship between those and

<sup>13</sup> carcinoma changes in the ovary.

I think that is sufficient support for concerns going back to the 1960s if it's a 1971 publication.

Q. You have reviewed the epidemiologic literature -- some of the epidemiologic literature looking at talcum powder use and ovarian cancer, correct?

A. Correct.

21

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<sup>22</sup> Q. That literature shows -- or strike <sup>23</sup> that.

Some of that literature reports the

Page 100 of 110 Well, just reading this paragraph, I <sup>1</sup> relative risk in the range of 1.2 to 1.3; is that <sup>2</sup> published this book review one year into my <sup>2</sup> right? <sup>3</sup> teaching career in 1996 based on someone else's A. Yes. 4 <sup>4</sup> book about breast implant litigation. Q. And such a relative risk in that range is a weak relative risk, correct? I could quote other parts from this DR. THOMPSON: Object to form. <sup>6</sup> book review that I actually remember, which was 7 THE WITNESS: No. No. It <sup>7</sup> that the author of this book expected to think 8 indicates for a serious disease that with <sup>8</sup> that the plaintiffs' lawyers were the villains in 9 this situation and actually found her villains confidence intervals that fall between 10 elsewhere. 1.2 and 1.3, a serious disease with a 11 11 substantial prevalence, even if not But in terms of these particular 12 incredibly common across the population, <sup>12</sup> statistics, all I can say is, as I reported them 13 <sup>13</sup> in the book review, I talked about wide confidence that's a serious risk. <sup>14</sup> BY MR. HEGARTY: <sup>14</sup> intervals. And I talked about one study where I 15 talk about the upper bound of the confidence Well, that's not exactly what you said before, and I'll show you the context. interval, but don't give the lower bound. I marked as Exhibit No. 21 an So perhaps I said that then. article of yours entitled "Lessons From Breast <sup>18</sup> Perhaps I would still agree. Perhaps I wouldn't. Implant Litigation." Aren't you saying there, though, 20 (Document marked for that your take is that with regard to the study 21 described there that the link to the disease is identification as Sage Exhibit 21.) <sup>22</sup> BY MR. HEGARTY: possible, but unlikely, and at any rate cannot be 23 substantial? Do you recall this article? Q. 24 24 DR. THOMPSON: Object to form. That's a book review. A. Page 391 Page 393 THE WITNESS: Possible --Q. Book review. Okay. 2 2 If you look over at the second page well, again, it's a -- it's a (laugh) <sup>3</sup> of that document, that book review, the paragraph 3 book review of someone else's book where <sup>4</sup> on the left-hand side where we say "What do we 4 my points in the book review are not <sup>5</sup> know in 1996?" Do you see that paragraph? 5 predominantly epidemiologic. 6 But I say what I say, and in A. 7 You note in that paragraph towards Q. this instance, we know that at least two the bottom that: 8 studies that are -- that I refer to in 9 "The most recent and largest study this paragraph have wide confidence 10 <sup>10</sup> calculated a relative of risk of 1.24 for intervals and the third is whatever I say 11 <sup>11</sup> self-reported disease and established with 95 <sup>12</sup> percent confidence an upper bound of 1.41. In 12 And I draw some inference, 13 <sup>13</sup> other words, a causal effect between breast which, as I just said, if I were to go 14 <sup>14</sup> implants and connective tissue disease is back and revisit the data and revisit <sup>15</sup> possible, but unlikely, and at any rate cannot be 15 these studies, I might or might not write

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Correct?

<sup>16</sup> substantial."

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- 18 That's what I say here, interpreting <sup>19</sup> the information in Angell's book at the time.
- And you're saying there that a study <sup>21</sup> that reports a relative risk of 1.24, while it <sup>22</sup> indicates a disease is possible, you're saying <sup>23</sup> it's unlikely, at any rate cannot be substantial, 24 correct?
- your words. It's not quoted from the book you reviewed, right?

Correct.

BY MR. HEGARTY:

Q.

A.

it the same way today.

- 22 This is your take on the book that O. 23 you reviewed, right?
  - A. It is a small piece of a book review

But the words that I read to you are

Page 394 Page 396 <sup>1</sup> stated. <sup>1</sup> essay that is mainly about other topics. 2 MR. HEGARTY: You mentioned or I just come back to the point we've 3 we talked earlier in the deposition about <sup>3</sup> discussed at several junctures, though we're now 4 the O'Brien study. I'll mark that study <sup>4</sup> sort of doing skip-around questioning, which is, 5 <sup>5</sup> I'm not offering a scientific expert opinion on as Exhibit No. 22. 6 (Document marked for causation. 7 Did you do any sort of analysis identification as Sage Exhibit 22.) O. BY MR. HEGARTY: weighing the strengths and weaknesses of the 9 O'Brien study? Do you in your report anywhere 10 10 reference this study? DR. THOMPSON: Object. Form. 11 I don't reference it directly. It's THE WITNESS: I read the 12 an analysis of pooled data. I spent a fair amount study. I mean, again, it's -- it's a 13 of time reading this when I was evaluating the pooled sample study to go back, you know, science and -- and the case. 14 and it's based on cohort studies that 15 15 You don't even cite this article in have their own characteristics and have O. 16 your reference materials, though, do you? their own weaknesses. 17 17 I'd have to look. If I don't, I It is a peer-reviewed article. 18 18 don't. It was worth my attention, and it should 19 19 have been noticed to you as among the Q. Do you want to look? 20 20 I did -- well. material I considered. 21 21 (Reviews document.) Beyond that, you'd have to ask 22 22 Apparently, I don't. other questions. 23 23 BY MR. HEGARTY: You do cite --Q. 24 24 A. I should have. My apologies. Q. If you look at paragraph 71 of your Page 397 Page 395 <sup>1</sup> report, you make the statement in that paragraph I was going to say: You cite a <sup>2</sup> number of other epidemiologic studies in your list <sup>2</sup> that "studies of cosmetics are infrequent and <sup>3</sup> of materials, correct? <sup>3</sup> poorly funded compared to drugs." A. Yes. What's your authority for that <sup>5</sup> statement? Certainly an article from 2020 from O. <sup>6</sup> JAMA is an article that should be referenced as It's consistent with everything I've A. <sup>7</sup> you would reference other articles of an <sup>7</sup> read in reviews of cosmetic regulation and, frankly, it's derivative of extensive expertise <sup>8</sup> epidemiologic nature that you included in your materials, correct? <sup>9</sup> with the drug regulatory regime, which requires 10 studies and the cost of which are constant matters DR. THOMPSON: Object to form. 11 THE WITNESS: I -- I agree of public comment. 12 12 this is an article that would be worth Do you have an opinion as to -- wait 13 referencing as material considered. 13 a minute. Strike that. <sup>14</sup> BY MR. HEGARTY: Is it your opinion that Johnson's 15 <sup>15</sup> Baby Powder in 2019 should have carried a warning And why did you not reference it? 16 DR. THOMPSON: Object to form. about the risk of ovarian cancer? 17 17 THE WITNESS: I can't answer MS. PARFITT: Objection. 18 18 DR. THOMPSON: Object to form. that. Might be an oversight. Might just 19 19 be -- I don't have an answer for that. I THE WITNESS: It is my 20 do -- I do -- I do recall reading --20 opinion that in 2019 and many years 21 21 reading this but -before that Johnson & Johnson had a legal <sup>22</sup> BY MR. HEGARTY: 22 obligation to disclose that safety had 23 23 not been determined. Q. Do you -- I'm sorry. 24 24 -- but the conclusions are as A. It is my opinion that with

Page 400 1 respect to warnings, instructions, or <sup>1</sup> things that Johnson & Johnson could have and --2 <sup>2</sup> could have done, and I would have applauded any of other mitigation options, such as 3 reformulation or withdrawal, Johnson & <sup>3</sup> them. 4 Johnson had to do something. I think it's worth pointing out that <sup>5</sup> BY MR. HEGARTY: <sup>5</sup> seriously studying the problem in ways that they <sup>6</sup> did not study the problem would have been a good And do you have an opinion as to <sup>7</sup> what information should have been included on the <sup>7</sup> start, but as for the rest of the mitigation <sup>8</sup> package for consumers as it relates to the <sup>8</sup> measures ranging from disclosure to warning to <sup>9</sup> analysis that you have done in this case? <sup>9</sup> instruction to reformulation to withdrawal, that 10 In other words, do you have specific was up to your client. <sup>11</sup> language that you believe should have been What are you relying on for saying <sup>12</sup> included on Johnson & Johnson's packaging for its 12 that Johnson & Johnson did not seriously study its <sup>13</sup> Johnson's Baby Powder and Shower to Shower talcum powder products? 14 products? A lot of this came out of the Wille 15 MS. PARFITT: Object to form. 15 testimony, but a lot of it also came out of the 16 THE WITNESS: I believe the <sup>16</sup> history of the different studies, and the fact 17 740.10 language should have been <sup>17</sup> that beyond those early studies of surgical 18 gloves, I was not made aware of any serious included. I think that was a direct 19 regulatory obligation. research contributions that Johnson & Johnson had 20 20 made. I think other language should 21 21 have been offered by Johnson & Johnson to Q. When you say you were not made aware 22 <sup>22</sup> of, that's -- you're referring to materials that better inform consumers about -- about 23 you have reviewed, correct? possibilities of harm, in other words, 24 24 Α. about risk, about ways to mitigate that Yes. Page 399 Page 401 1 risk in terms of Instructions for Use or If you look at paragraph 80 of your 2 report -- I'm sorry. Let's not -- let's not go nonuse. 3 But I wasn't asked to create <sup>3</sup> there yet. I think I skipped over a couple 4 language for your client, and I think the points. 5 major lesson is that many things that My methodology is to take the tabs 6 your client could have done would satisfy off the bottom of my notes. 7 me, but doing nothing does not satisfy (Laugh). 8 8 MR. TISI: Where was it 9 <sup>9</sup> BY MR. HEGARTY: published? 10 Q. I was going to ask. My next MR. HEGARTY: It's not been question is: Do you have an opinion as to what 11 published. 12 specific language should have been included on 12 MR. TISI: Well, then strike 13 13 Johnson's Baby Powder and Shower to Shower during you. 14 14 the time it was being sold in the United States MR. HEGARTY: It's not 15 and Canada? 15 reliable. 16 16 MS. PARFITT: Objection. THE WITNESS: My methodology 17 17 DR. THOMPSON: Object to form. is, I need a little more Diet Coke. 18 18 THE WITNESS: No. MR. HEGARTY: I realize at 19 19 BY MR. HEGARTY: times when I finish a deposition and I 20 And do you have an opinion as to 20 figure out that I did miss things to ask. <sup>21</sup> what specific mitigation activities Johnson & 21 BY MR. HEGARTY: <sup>22</sup> Johnson should have initiated with regard to its 22 So if you look at paragraph 70 of <sup>23</sup> talcum powder products? 23 your expert report. 24 Again, there are a wide range of 24 A. Yes.

Page 404 I think we've established that you A. I do. <sup>2</sup> have not read all of the expert reports provided O. And are you in that paragraph <sup>3</sup> by the Johnson & Johnson defendants in this <sup>3</sup> referencing the long latency between talcum powder <sup>4</sup> use and the development of ovarian cancer, or <sup>4</sup> litigation? <sup>5</sup> something else? A. Yes. 6 Essentially -- essentially that, but Q. And particularly you have not read <sup>7</sup> the reports of Johnson & Johnson experts where <sup>7</sup> I've spent a fair amount of teaching time studying they say that talcum powder use is safe, correct? <sup>8</sup> and teaching occupational safety and health 9 <sup>9</sup> examples that distinguish between workplace MS. PARFITT: Objection to <sup>10</sup> accidents and workplace diseases, and long 10 form. 11 <sup>11</sup> latencies for studying those types of association THE WITNESS: I have read 12 some testimony regarding their assertions <sup>12</sup> are frequently an obstacle to defend epidemiology, 13 and many of those cases involve cancer. that talcum powder is safe. I have seen 14 14 perhaps an expert report, but nothing Do you have an opinion in this case 15 <sup>15</sup> as far as the latency between talcum powder use immediately springs to mind. 16 It has been the company's and ovarian cancer development? 17 17 A. consistent position essentially since No. 18 18 Do you have any opinion as to the time immemorial, which is to me a big O. 19 minimum talcum powder use that is -- that is part of the problem here. 20 BY MR. HEGARTY: required to increase -- that will increase the 21 <sup>21</sup> risk of ovarian cancer? Q. And with regard to Johnson & 22 <sup>22</sup> Johnson's experts who have -- who testified and No. 23 <sup>23</sup> prepared reports saying that talcum powder is DR. THOMPSON: Object to form. <sup>24</sup> safe, is it your contention that they are not <sup>24</sup> BY MR. HEGARTY: Page 403 Page 405 <sup>1</sup> being truthful in making those statements? In your opinion, though, based on DR. THOMPSON: Object to form. this paragraph, it is impossible to substantiate 3 THE WITNESS: Could you ask <sup>3</sup> the safety of talc, correct? 4 that perhaps a slightly different way? DR. THOMPSON: Object to form. 5 <sup>5</sup> BY MR. HEGARTY: THE WITNESS: Could I ask you 6 to repeat that question? Q. Sure. BY MR. HEGARTY: To the extent an expert for Johnson & Johnson said in their report or their testimony O. Sure. <sup>9</sup> that talcum powder use is safe, is it your Based on the statements you're <sup>10</sup> contention that they're not being truthful in making about the -- well, you actually say that making those statements? expeditious -- let me start over again. 12 DR. THOMPSON: Object to form. 12 A. Ah. Now I know. 13 13 BY MR. HEGARTY: "Expeditious and definitive studies 14 In making that statement? to determine safety are impossible given long Q. 15 latency for carcinogenesis and other research A. I simply view it as their expressed 16 16 challenges." opinion. 17 17 Q. Which you are doing here today So aren't you saying there that it is impossible to substantiate the safety of talc yourself, correct? 19 because of the latency period? Α. Indeed. 20 DR. THOMPSON: Object to form. Q. Now we can turn over to paragraph 80 21 of your report. THE WITNESS: I'm not saying 22 22 that. From an ex ante position, all of You reference in that paragraph what

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Do you see that?

24

you call "long latency for carcinogenesis."

this is possible, as it would be for any

cosmetic ingredient or cosmetic product.

Page 406 Page 408 1 1 You say in the first paragraph: That paragraph that you 2 2 referenced is the continuation of the "As stated previously beginning in 3 <sup>3</sup> the 1960s" -- I'm sorry. You state in the first paragraph above, which is explaining why 4 this situation does not under any sentence: 5 circumstances fall within the exception "As stated previously, beginning in 6 <sup>6</sup> the 1960s, the scientific literature presented of the regulation provides to the 7 obligation to provide the "safety not <sup>7</sup> evidence of talcum powder containing asbestos and determined" warning. fiber talc -- fibrous talc." You go on to say: BY MR. HEGARTY: 10 "Johnson & Johnson testing results But you mention that you have taught and internal discussions also demonstrate the with regard to latency in cancer. 12 Is it your testimony that with a presence of and concern about the presence of possible -- well, let me back up. asbestos in talc fibers." 14 You agree that latency as it relates Did I read that correctly? 15 to exposure and a disease assumes that the A. 16 exposure causes the disease, correct? What documents have you reviewed 17 Yes. that show internal discussions within Johnson & 18 Johnson that demonstrate the presence of and Q. And in your opinion, how do you substantiate the safety of a product with the concern about the presence of asbestos and talc possibility of a long latency period? <sup>20</sup> fibers? 21 21 DR. THOMPSON: Object to form. A. The presence of that exhibit that we 22 <sup>22</sup> discussed earlier that had the Hopkins assessments THE WITNESS: There is always 23 the possibility of a long latency period. of the various prior testing that Johnson & 24 <sup>24</sup> Johnson had done. In terms of concern about the We could pick any cosmetic, Page 409 Page 407 1 call it X, and any latent disease, call <sup>1</sup> presence, I did early in my engagement review some 2 <sup>2</sup> internal corporate documents that I read as it Y, and at the moment you begin to sell 3 the product, you do what you can to <sup>3</sup> expressing concern. 4 substantiate the safety of the product, Do you cite any of those corporate 5 and you do not observe the disease while documents in the body of your report? 6 occurring and you regard having done A. No. 7 something to the product that If we turn over to paragraph 121 of 8 substantiated safe. your report, you say in that paragraph: 9 "In sum, Johnson & Johnson But as information surfaces, 10 manipulated asbestos testing and associated as it has in abundance with respect to 11 talcum powder exposure and ovarian publicity so that 'none detectable' would be 12 cancer, that calls into question your interpreted as 'none." 13 13 prior substantiation determination and What associated publicity are you 14 that's when you have the obligation to referring to in that paragraph? 15 15 I'm -- I'm referring to things that disclose. <sup>16</sup> BY MR. HEGARTY: such as the Facts About Talc website, admittedly 17 not a comprehensive overview. But in addition the So it's not your testimony then before a cosmetic manufacturer can sell a product, Koberna deposition testimony regarding marketing they have to weigh -- they have to test it for 10, activities, you know, included marketing efforts 20, 30, 40 years? that -- that certainly did not refer to the 21 possibility of adulteration of asbestos. A. Certainly not. 22 22 If you could look at paragraph 112 Q. And whose deposition did you just 23 of your expert report. <sup>23</sup> mention? 24 Yes. 24 A. A. Koberna.

Can you show me that in your <sup>2</sup> reliance materials, the exhibit we've been looking 3 at?

4 I believe the deposition was subsequent to the submission of the report.

So -- so perhaps I guess the more <sup>7</sup> accurate way to give my answer is, I didn't consider it in drafting the report, but it was subsequently made available to me.

10 And how do you spell the name that you're referring to?

12 I think it's K-o-b-e-r-n-a. It was <sup>13</sup> an uncompleted deposition and, frankly, I found it <sup>14</sup> incredibly interesting given my mom's career in advertising.

16 MR. HEGARTY: I'm going to 17 mark as Exhibit 23 a folder of 18 supplemental materials that we were 19 provided by counsel for the plaintiffs in 20 this case.

21 (Document marked for 22 identification as Sage Exhibit 23.)

<sup>23</sup> BY MR. HEGARTY:

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24

And it's just a printout of the page Q.

<sup>1</sup> are you able to identify -- let me back up.

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Have you received additional <sup>3</sup> materials from plaintiffs' counsel since you signed your report on July 2, 2021?

I said before that I had, and I repeat that answer.

You identified some of those. But do you know whether all of the

materials you received since July 2, 2021 are in this Exhibit 23?

11 A. I have worked with counsel as best <sup>12</sup> we could to make sure that anything that I saw subsequently was properly cataloged and properly shared with your client.

15 But do you -- are you able to recall <sup>16</sup> anything else that you have reviewed since you signed your expert report on July 2, 2021, besides <sup>18</sup> what you've already provided to us -- to me in this deposition?

A. Right now, no.

21 Q. Is there anything else that stands 22 out to you?

You mentioned that -- you mentioned <sup>24</sup> some things. You mentioned the Koberna

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<sup>1</sup> in the matter that they provided to us in a <sup>1</sup> deposition.

<sup>2</sup> Dropbox. When you pull up the particular heading <sup>3</sup> for the supplemental materials, this is what you <sup>4</sup> can print out.

5 Do you understand that?

6 Yes. A.

And do you recall after the initial <sup>8</sup> supplying of materials to you whether there were <sup>9</sup> supplemental materials provided to you at a later 10 date?

11 As I said at some point earlier 12 today, I've continued to -- to research the basis 13 for the opinions that I have given, and I've <sup>14</sup> continued to ask questions again about both sides 15 of the issue.

And one of the areas that I do not <sup>17</sup> feel I had sufficiently explored for the original <sup>18</sup> report were marketing activities because there was 19 not a lot of content I could review for that, and <sup>20</sup> this was a subsequent deposition. And so when it <sup>21</sup> came along, I was very pleased to receive it and 22 to read it in full. 23 It should have been provided to you.

What materials have you received or

Anything else you recall -- well,

<sup>3</sup> let me ask it this way.

Is there anything else you are <sup>5</sup> relying on or using as a resource material for purposes of what you testified here today that you <sup>7</sup> have received since signing your July 2, 2021

expert report?

Everything that I have considered is something that I have discussed with plaintiffs' counsel in order so that that could be properly listed and shared as required. I don't know more 13 than that.

14 Is there anything that you know of O. <sup>15</sup> sitting here today that you rely upon or you <sup>16</sup> considered since your July 2, 2021 report was signed that you know we have not talked about today, that you have not referenced or I have not 19 asked about?

20 Certainly -- certainly anything that <sup>21</sup> -- that I can think of and that was significant <sup>22</sup> enough that it matters to me sitting here is <sup>23</sup> something that you've seen or received. 24

We talked about the CIR and are you

Page 414 Page 416 <sup>1</sup> aware that the -- or is it --<sup>1</sup> similar underlying data and reached rather Do you have any opinion with regard <sup>2</sup> different conclusions. And I set forth in that <sup>3</sup> to the way that CIR is funded, that is, that you <sup>3</sup> comparison a number of areas of concern, but the <sup>4</sup> find to be part of your opinions as it relates to <sup>4</sup> detail that exists in my Appendix 2 is not detail <sup>5</sup> the CIR review for talc and ovarian cancer -- I'm that I could reproduce for you right now. <sup>6</sup> sorry -- talc and the safety of talc? And is it your -- did you read the MS. PARFITT: Objection. <sup>7</sup> entirety of the CIR safety assessment of talc as 8 used in cosmetics? Form. 9 I read as much of it as I was THE WITNESS: I do not 10 10 currently recall the details of the CIR capable of reading at the time. (Laugh). 11 funding support. The generally close And understand and understood. 12 12 connection between the CIR, the trade But my question is: Did you read 13 <sup>13</sup> the entirety of it? association, and the trade association's 14 14 members is concerning to me, as it was A. I made a point of reading it, 15 15 concerning to FDA in that 1998 internal seriously. 16 review. 16 O. Oh, did you read every page, every 17 17 BY MR. HEGARTY: word on every page? 18 You looked at the -- the document 18 A. No. 19 Did you read every word of every setting out the CIR analysis by Fiume, correct? 20 If you could provide it, I would page of the Health Canada safety assessment? 21 21 appreciate it. Α. No, but both of these are -- are 22 <sup>22</sup> materials that I considered highly relevant and MR. HEGARTY: I do have it. 23 <sup>23</sup> important to my assessment and opinions, and I I'll mark as Exhibit No. 24 24 the Fiume article. <sup>24</sup> engaged seriously with both of them. Page 415 Page 417 1 And if you look over Appendix 1 of (Document marked for 2 your report, which is "Summary of scientific identification as Sage Exhibit 24.) <sup>3</sup> evidence relating to talcum powder and its <sup>3</sup> BY MR. HEGARTY: 4 association with ovarian cancer"? Q. Do you recall reading that article? 5 (Reviews document.) A. Yes. A. 6 Q. There's a section there where you Yes. <sup>7</sup> talk about some studies dealing with migration of Do you know any of the individuals 8 whose names are listed at the top of that exhibit? particles from the vagina to the ovaries. 9 9 Do you see that section paragraph 7? A. No. 10 10 Do you have any criticism of the Yes. A. capabilities of any of the individuals listed at 11 O. Before this, before being hired to the top of that article? serve as an expert witness in this case, had you 13 MS. PARFITT: Objection to ever in any of your work looked at articles <sup>14</sup> regarding the migration of particles within 14 form. 15 15 tissue? THE WITNESS: I wouldn't have 16 16 Certainly, but I couldn't specify a basis for criticism. which. My father back in the 1950s did studies of 17 BY MR. HEGARTY: 18 lymphatic spread using colloidal gold particles. Is it your opinion that the CIR panel did not do a proper analysis as reflected or 19 Well, I wasn't asking about what as set out in this -- this document? 20 your father did. 21 21 So the way I would answer that I asked you if you had any <sup>22</sup> question would be to reference Appendix 2 in my <sup>22</sup> experience in looking at the migration of <sup>23</sup> report, which is a specific comparison of the CIR <sup>23</sup> particles within the body prior to being hired as <sup>24</sup> and Health Canada assessments, because they took <sup>24</sup> an expert in this case.

Page 420 In connection with my -- my medical Sure. This is without the loose A. <sup>2</sup> education and my medical interests, from time to materials, right? <sup>3</sup> time. I'm sorry. Correct. 4 Q. And had you reviewed any of the (Reviews documents.) <sup>5</sup> studies that you cite in this part of your report The underlining in the notes that <sup>6</sup> prior to being -- that is, in paragraph 7 -- prior are in your report, are those or those are from <sup>7</sup> to being contacted to serve as an expert witness you, correct? 8 in this case? In the report, in the tab containing A. the report, yes. The dots on the CV are also from A. No. 10 O. You had -- we had designated as <sup>11</sup> Exhibit No. 11 the notebook of materials that you 11 O. And when did you make these notes 12 have in front of you? and these underlining in relation to the Yes. 13 deposition? A. 14 14 A. Do you recall that? Roughly -- well, since we Q. 15 <sup>15</sup> rescheduled, it would have been, roughly, a week I want to go ahead and designate as <sup>16</sup> Exhibit No. 25 the loose materials that you have before the original scheduled date. 17 brought with you. And I'm almost finished. 18 18 Okay. (Reviews document.) A. 19 19 (Document marked for I'll give that back to you. 20 20 identification as Sage Exhibit 25.) And can you hand me the loose <sup>21</sup> BY MR. HEGARTY: materials that we designated as Exhibit No. 25? 22 22 Yes. Here. My report is in --Q. So would you keep that together --23 23 Q. A. 24 24 -- a couple of these. Q. -- as a separate set of documents? A. Page 419 Page 421 A couple of exhibits are there. Yes. I'm trying -- I'm trying to Q. 2 <sup>2</sup> keep it separate from. I think this --A. 3 3 Looks like more than a couple. Keep it separate from the exhibits Q. Q. 4 that --A. Yeah, I think it's that. 5 And with regard to the FDA's Α. Yeah. I think we're okay on that. O. <sup>6</sup> I'll do my -- I do my -- I don't think anything cosmetic program that you've been talking about, <sup>7</sup> was this a document that plaintiffs' counsel <sup>7</sup> has got mixed up yet but... Well, anything that you have over provided to you? 9 there should be marked as an exhibit sticker. I A. Yes. 10 10 want to make sure that you have anything --O. This is actually an exhibit, too. 11 11 A. Right. A. Oh, sorry. 12 -- that you brought with you loose 12 O. 0. So is that. And that. 13 13 that was not marked as an exhibit --A. Yeah, this was an exhibit, also. 14 14 And I believe those are all the A. Correct. O. 15 questions I have. Thank you, Doctor. O. -- we'll designate as Exhibit <sup>16</sup> No. 25. 16 My pleasure. 17 17 A. Certainly. (Discussion off the record) 18 18 And with regard to the loose DR. THOMPSON: I have a few Q. 19 materials and the notebook, are those all the questions, but before that a materials that you brought with you to the 20 housekeeping. I believe you have the 21 supplemental reliance list. <sup>21</sup> deposition? 22 22 MR. HEGARTY: You thought you A. 23 23 And can I look just for a second at had sent us a list? Q. 24 <sup>24</sup> your notebook? MS. PARFITT: Right because

Page 422 Page 424 1 the NCI article that you talked about O. And I'm going to show you this 2 <sup>2</sup> exhibit, Dr. Sage, and would you look at that and earlier, the Koberna, all of that, that's 3 <sup>3</sup> whether you've ever seen that exhibit before right all on there. That, hopefully, will 4 clarify. That may have happened when, 5 you know, the first deposition was A. The actual -- this actual exhibit I 6 <sup>6</sup> don't -- I don't recall, but it may be in my scheduled and then maybe... 7 MR. HEGARTY: I did get last <sup>7</sup> materials. 8 night a couple of articles by e-mail. O. Would you look at those listing of 9 <sup>9</sup> materials and tell me whether you reviewed all of MR. TISI: That was different. 10 them, some of them, none of them? That was different. 11 11 Α. (Reviews document.) MR. HEGARTY: That was 12 12 Several of them look familiar. different. 13 DR. THOMPSON: No. This was 13 Several of them are things that I have read all or 14 parts of. Certainly these deposition transcripts done -- this was done --15 <sup>15</sup> were made available to me. The Koberna one was MR. TISI: This was done 16 before. 16 the one I spent the most time with, and then a lot 17 <sup>17</sup> of the ones regarding more recent reform proposals DR. THOMPSON: -- prior to the 18 and the like I've engaged with extensively. first scheduled deposition. 19 MR. HEGARTY: I don't remember 19 Do you recall when it was in 20 relation to your expert report when you received seeing it. I'm not saying that you did 21 <sup>21</sup> these additional materials? not send it. 22 22 It was sporadically after that. It MS. PARFITT: Yeah. 23 MR. HEGARTY: But I don't wasn't as a batch. 24 24 remember seeing it. O. Have you received any additional Page 425 Page 423 1 <sup>1</sup> materials from plaintiffs' counsel since or in the Is it okay I mark it as an 2 <sup>2</sup> last two weeks? exhibit? 3 DR. THOMPSON: Yes. 3 A. Not that I recall. 4 4 MR. TISI: Although we did MR. HEGARTY: Is it okay if I 5 send you stuff last night, right? ask the doctor a couple questions about 6 it when you're done? Or I can do it <sup>6</sup> BY MR. HEGARTY: 7 right now. You mentioned that you had read some 8 DR. THOMPSON: No. You can go of the transcript of Koberna. 9 Did you read the trial transcripts ahead do it. 10 of the Cadagin case that are referenced here? MR. HEGARTY: I can do it 11 They were sent to me. I don't right now. 12 DR. THOMPSON: That was in his <sup>12</sup> believe I read them. 13 13 notebook also but that's a separate copy. Q. And did you ask for any of these 14 MR. HEGARTY: Okay. Yeah. It <sup>14</sup> materials? 15 would be helpful if I could just clean 15 Α. I asked for a lot of these 16 that and make a record of it. <sup>16</sup> materials, not by name, but I asked for -- I asked 17 <sup>17</sup> for the Koberna materials and anything else (Discussion off the record). 18 related to marketing. I asked for a lot of the MR. HEGARTY: So I'm marking 19 <sup>19</sup> reform efforts. And I asked for, you know, as Exhibit No. 26 the list of materials 20 that Dr. Thompson provided to me that she updated scientific literature. This was, I'm 21 <sup>21</sup> sure, provided in due course because of that indicated had been provided to us before. 22 <sup>22</sup> request. (Document marked for 23 23 identification as Sage Exhibit 26.) Did you read all the scientific O. <sup>24</sup> BY MR. HEGARTY: <sup>24</sup> literature that's referenced in this exhibit?

| Pageid. 232   |  |               |
|---|--|---------------|
| Page 426  1 A. Not not all of it.                             | becomes available?   | Page 42       |
| Q. In looking at these articles, can                          | <sup>2</sup> A. I do reserve that right.                       |               |
| you tell me which of these you did read?                      | Q. Would that include any                                      | y raviaw of   |
| <sup>4</sup> A. (Reviews document.)                           | _  |               |
| · · · · · · · · · · · · · · · · · · ·                         | detense expert reports in the reg                              | uratory area? |
| Sitting field right flow, I can't.                            | A. 168, Certainly.   | To fouth on   |
| MIK. HEOAKTT. Okay. All                                       | DK. HIOMFSON. 1  | No Turmer     |
| <ul> <li>right. Thank you.</li> <li>EXAMINATION</li> </ul>    | questions.   | - C41         |
|   | WIK. HEOAKI I. IN  | o turtner     |
| DR. THOMI SON. Let the go ahead                               | 9 questions.   |               |
| and mark one of the documents that you                        |  | `             |
| brought with you that was roose,                              | $\begin{bmatrix} 11 \\ 12 \end{bmatrix}$ (Time noted: 5:33 p.m | .)            |
| Di. Sage, and this is the TDA Cosmettes                       |  |               |
| 1 Togram. Current 1 Tojects and Resources                     |  |               |
| and a Discussion of the 'Model' Program,                      | 14   |               |
| FDA Cosmetics Mission Statement."                             |  |               |
| (Document marked for  | 16   |               |
| identification as Sage Exhibit 28.)                           | 17   |               |
| 18 BY DR. THOMPSON:   | 18   |               |
| Q. Did you consider this document in                          | 19   |               |
| <sup>20</sup> forming relating the opinions that you gave     | 20   |               |
| 21 today?   | 21   |               |
| <sup>22</sup> A. Yes.   | 22   |               |
| Q. Is it confirmatory of the opinions                         | 23   |               |
| <sup>24</sup> that you provided in your report?               | 24   |               |
| Page 427  | 7  | Page 429      |
| <sup>1</sup> A. Yes, it is.                                   | 1 ERRATA SHEET   |               |
| <sup>2</sup> Q. And is it confirmatory of the                 | 2  |               |
| <sup>3</sup> opinions that you've offered here today as well? | <sup>3</sup> Page NoLine NoChange to:_                         |               |
| <sup>4</sup> A. Yes.  | 4  |               |
| <sup>5</sup> Q. You mentioned earlier that you                | 5 Page NoLine NoChange to:_                                    |               |
| <sup>6</sup> looked at the Johnson & Johnson website that was | 6  |               |
| <sup>7</sup> Facts About Talc.                                | 7 Page NoLine NoChange to:_                                    |               |
| 8 And did that website include                                | 8  |               |
| <sup>9</sup> corporate documents?                             | 9 Page NoLine NoChange to:_                                    |               |
| 10 A. Yes.  | 10   |               |
| Q. And were those documents selected by                       | 11 Page NoLine NoChange to:_                                   |               |
| <sup>12</sup> Johnson & Johnson to include on the website?    | 12   |               |
| 13 A. Yes.  | 13 Page NoLine NoChange to:_                                   |               |
| Q. Did you review the documents from                          | 14   |               |
| 15 that website?  | <sup>15</sup> Page NoLine NoChange to:_                        |               |
| A. Yes, some of them. I don't recall                          | 16   |               |
| 17 how many there were but, yes.                              | 17 Page NoLine NoChange to:_                                   |               |
| Q. And, Dr. Sage, were the opinions in                        | 18   |               |
| 19 your report and the opinions that you gave today           | 19 Page No. Line No. Change to:                                |               |
| 20 given to a reasonable degree of scientific and             | 20   |               |
| 21 professional certainty?                                    | 21 Page No. Line No. Change to:                                |               |
| 22 A. Yes, they were.   | 22   |               |
| Q. And do you reserve the right to                            | 23 Page No. Line No. Change to:                                |               |
| 24 amend or supplement your report if new information         | 24   |               |
| amena of supplement your report if new information            |  |               |

|          | FageID. 232330                                    |  |  |  |
|----------|---|--|--|--|
|          | Page 430  |  |  |  |
| 1        | DECLARATION UNDER PENALTY OF PERJURY              |  |  |  |
| 2        |   |  |  |  |
| 3        |   |  |  |  |
| 4        | I declare under penalty of                        |  |  |  |
| 5        | perjury that I have read the entire transcript of |  |  |  |
| 6        | my Deposition taken in the captioned matter       |  |  |  |
| 7        |   |  |  |  |
| 8        | the same is true and accurate, save and           |  |  |  |
| 9        | except for changes and/or corrections, if         |  |  |  |
| 10       | any, as indicated by me on the DEPOSITION         |  |  |  |
| 11       | ERRATA SHEET hereof, with the understanding       |  |  |  |
| 12       | that I offer these changes as if still under      |  |  |  |
| 13       | oath.   |  |  |  |
| 14       |   |  |  |  |
| 15       | Signed on the day of                              |  |  |  |
| 16       | , 2021.   |  |  |  |
| 17       |   |  |  |  |
| 18       |   |  |  |  |
| 19       | WILLIAM M. SAGE, MD, JD                           |  |  |  |
| 20       |   |  |  |  |
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| 22       |   |  |  |  |
| 23       |   |  |  |  |
| 24       |   |  |  |  |
|          | Page 431  |  |  |  |
| 1        | CERTIFICATE OF REPORTER                           |  |  |  |
| 2        | DISTRICT OF COLUMBIA )                            |  |  |  |
| 3        | I, DENISE DOBNER VICKERY, CRR/RMR and             |  |  |  |
| 4        | Notary Public, hereby certify the witness was by  |  |  |  |
| 5        | me first duly sworn to testify to the truth; that |  |  |  |
| 6        | the said deposition was recorded stenographically |  |  |  |
| 7        | by me and thereafter reduced to printing under my |  |  |  |
| 8        | direction; and that said deposition is a true     |  |  |  |
| 9        | record of the testimony given by said witness.    |  |  |  |
| 10       | I certify the inspection, reading and             |  |  |  |
| 11       | signing of said deposition were NOT waived by     |  |  |  |
| 12       | counsel for the respective parties and by the     |  |  |  |
| 13       | witness; and that I am not a relative or employee |  |  |  |
| 14       | of any of the parties, or a relative or employee  |  |  |  |
| 15<br>16 | of either counsel, and I am in no way interested  |  |  |  |
| 17       | directly or indirectly in this action.            |  |  |  |
| 18       |   |  |  |  |
| 19       |   |  |  |  |
| 20       |   |  |  |  |
| 21       | Denise Dobner Vickery, CRR/RMR                    |  |  |  |
|          | Notary Public in and for the                      |  |  |  |
| 22       | District of Columbia                              |  |  |  |
| 23       |   |  |  |  |
| 43       |   |  |  |  |
| 24       | My Commission expires: February 28, 2023          |  |  |  |